# EPA Registration No. 70506-93 vol. 1



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

SEP 2 0 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

United Phosphorus Inc. c/o Michael Kellogg Pyxis Regulatory Consulting 4110 136<sup>th</sup> St. N.W. Gig Harbor, WA 98332

Gentlemen:

Subject:

Add New Uses and Revised Labeling

Clopyralid Technical

EPA Registration No 70506-93

Your Submission Dated September 8, 2005

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you:

- 1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) or 4(a) when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
  - The Conditions of Sales and Limited Warranty section is unacceptable since it only warrants the chemical description on the label. This negates the directions for use and precautionary statements required on pesticide labeling by FIFRA. Refer to the enclosed 1966 PR Notice for acceptable statements.
- 3. Submit one (1) copy of your final printed labeling before you release the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter please contact Mr. James Stone at 703-305-7391.

Sincerely yours,

Joanne I. Miller

Product Manager (23) Herbicide Branch

Registration Division (7505C)

anne J. Miller

**Enclosure** 

## Clopyralid Technical

ACTIVE INCREDIENT:

TIOTA I DI TIOTALITA	
Clopyralid: 3,6-dichloro-2-pyridinecarboxylic acid	96.0%
INERT INGREDIENTS:	4.0%

## KEEP OUT OF REACH OF CHILDREN

	FIRST AID
If in eyes:	<ul> <li>Hold eye open and rinse slowly with a steady, gentle stream of water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a physician or poison control center immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>DO NOT induce vomiting unless told to do so by poison control center or physician.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably, mouth-to-mouth, if possible.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If on skin or clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Wash skin with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
	Probable mucosal damage may contraindicate the use of gastric lavage. container or label with you when calling a poison control center or doctor,
	nent. rgency: spill, leak, fire, exposure or accident, call CHEMTREC at 1-800-

See side panel for additional precautionary statements.

#### Manufactured For:

United Phosphorus, Inc. 423 Riverview Plaza

Trenton, NJ 08611

1-800-247-1557 • www.upi-usa.com

EPA Reg. No. 70506-93 EPA Est. No.

ACCEPTED with COMMENTS In EPA Letter Dated:

SEP 2 0 2005 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

70506-93

Net Weight:

# PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals DANGER

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Do not get in eyes or on skin and clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

#### **Agricultural Uses**

Asparagus, barley, broccoli, broccoli raab, Brussels sprouts, cabbage, canola, cauliflower, Chinese cabbage, Chinese broccoli, collards, corn, fallow land, garden beets, grasses, kale, kohlrabi, mint, mizuna, mustard greens, mustard spinach, oats, pasture, rangeland, rape greens, spinach, stone fruits, sugar beets, tree plantations, turnips, and wheat. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult United Phosphorus, Inc. for instructions for formulation and other information.

#### Non-Agricultural Uses

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial manufacturing and storage sites, non-cropland, parks, rights-of-way, sod farms and roadsides; grass grown for seed; select ornamental plantings in landscapes and nurseries, forest sites; CRP acres. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s). Consult United Phosphorus, Inc. for instructions for formulation and other information.

This product must not be formulated into manufacturing-use products or end-use products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

- Do not use on residential turf
- Do not send clippings to a compost facility
- Do not collect grass clippings for mulch or compost
- Applicator must give notice to landowners/property managers to not use grass clippings for composting.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

#### PESTICIDE STORAGE

Store in a cool, dry, well-ventilated area.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

#### CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

#### CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that the seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

Rev. 8/05

# Fee for Service



This package includes the following	for Division
<ul><li>New Registration</li><li>Amendment</li></ul>	○ AD ○ BPPD ◎ RD
□ Studies? □ Fee Waiver? □ volpay % Reduction:	Risk Mgr. 23
Receipt No. S	- W 784063
EPA File Symbol/Reg. No.	70506-93
Pin-Punch Date:	9/9/05
This item is NOT subject to	FFS action.
Action Code:	Parent/Child Decisions:
Requested:	
Granted:	
Amount Due: \$	
Reviewer: Imiller	Date: 9-13-05
Remarks:	



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 15, 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MICHAEL KELLOGG UNITED PHOSPHORUS INC 423 RIVERVIEW PLAZA TRENTON, NJ 08611

PRODUCT NAME: AGVALUE CLOPYRALID TECHNICAL

COMPANY NAME: UNITED PHOSPHORUS INC

EPA FILE SYMBOL: 70506-93 EPA RECEIPT DATE: 09/09/05

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-6224.

Sincerely,

Furice

Front End Processing Staff Information Services Branch

Information Technology & Resources Management Division

SEPA	Environmenta	United States	•	,		<b>✓</b>	Registra Amend Other	ation	O. Approval expires 2-28- OPP Identifier Number
		Application	n for Pes	ticio	le - Sect	ion			
1. Company/Product Number 70506-93	or .		1	EPA F Mille	roduct Man	ager		3. Pr	oposed Classification
4. Company/Product (Name United Phosphorus, Inc		nnical	РМ	#	2	23			
5. Name and Address of Ap United Phosphorus, Inc c/o Pyxis Regulatory Co 4110 136th St. NW Gig Harbor, WA 98332	nsulting, Inc.	ode)	(b)( to: EF	(i), m	y product i	s sim	ilar or iden	tical in co	FIFRA Section 3(c)(3) imposition and labeling
Check if this	s is a new address		Section Pr		t Name _				
Notification - Explain  Explanation: Use addition Submission of label amer United Phosphorus, Inc.'s this amendment, nor will a Fast Track amendment of 2003. Please email fee	below.  nal page(s) if necessare dement to add additions Clopyr Ag (EPA Regidata need to be reviewed and is not subject to sa@PyxisRC.com if the	ry. (For section onal uses. The g. No. 70506- ewed to appro- a Pesticide R	e additional us 94) label approve the propose egistration Se	ses a oved ed lal ervice	by the Age beling, Unite Fee as def	encloney or	ed ation.  Now.  Dised Clopyr  n June 3, 2  osphorus, 1	alid Techr	o data are submitted with es this action qualifies as
1. Material This Product Wil	T	<del> </del>					т		
Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per . container	Water Solution Yes No If "Yes" Package wg		No. per container		2. Type of	Metal Plastic Glass Paper Other (S	
3. Location of Net Contents  Label	Information Container	4. Size(s) Ret	ail Container			5. Lo	On Labelin	bel Direction	
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stenci	raph glued led		Other				••••
			Section	- IV				HERE !	• • • • • · · · · · · · · · · · · · · ·
1. Contact Point (Complete	items directly below	for identificatio	n of individual	to be	contacted,	f nec	essary, to p	rocess this	appligation.)
Name Michael Kellogg			Title Agent						e No. (Include Area Code) 53-7369
l certify that the state I acknowledge that ar both under applicable	y knowlinglly false or	Certifica this form and misleading sta	all attachment	s the	reto are true shable by fir	, accu 1e or i	irate and co mprisonmer	mplete. nt or	6. Pate Application Received (Stamped)
2. Signature  Muhan A	Dogg		3. Title Agent						• • • •
4. Typed Name			5. Date						

September 8, 2005

Michael Kellogg

#### PYXIS REGULATORY CONSULTING, INC.

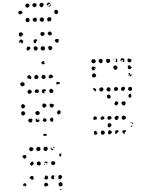
4110 136<sup>th</sup> St. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 www.PyxisRC.com

September 8, 2005



Joanne Miller (PM 23)
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 Bell Street
Arlington, VA 22202-4501



RE: United Phosphorus, Inc. – Clopyralid Technical (EPA Reg. No. 70506-93)
Application for a New Pesticide Registration

Dear Ms. Miller,

On behalf of United Phosphorus, Inc. we are submitting an amended label for Clopyralid Technical (EPA Reg. No. 70506-93) to add various crop and non-crop use sites. In support of this amendment, we submit the following documents:

- 1. Application for Amended Registration (EPA Form 8570-1)
- 2. One (1) copy of the Clopyralid Technical amended label with tracked changes [Editors Note: Added text is <u>underlined</u> and deleted text is denoted by <u>strike-through</u>]
- 3. Five (5) copies of the Clopyralid Technical amended label with changes incorporated
- 4. Certification with Respect to Citation of Data (EPA Form 8570-34)
- 5. Agency Internal Use Copy of the Data Matrix
- 6. Public File Copy of the Data Matrix
- 7. Letter of Authorization from Albaugh, Inc.

The additional uses added to the enclosed Clopyralid Technical label appear on United Phosphorus, Inc.'s Clopyr Ag (EPA Reg. No. 70506-94) label approved by the Agency on June 3, 2005. As no data are submitted with this amendment, nor will data need to be reviewed to approve the proposed labeling, United Phosphorus, Inc. believes this action qualifies as a Fast Track amendment and is not subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act of 2003.

We trust you will find this application complete. However, please feel free to contact me if you have any questions or need any additional information.

Sincerely,

Michael Kellogg

Enclosures

cc: Ann Tillman; United Phosphorus, Inc.

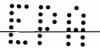


#### **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY** 401 M Street, S.W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of and 0.25 hours per response for reregistration and special review activities, including comments regarding burden estimate or any other aspect of this collection of informa Information Management Division (2137), U.S. Environmental Protection Agency, 40 Do not send the completed form to this address.	time for reading the ation, including sugge	instructions and completing the necessary forms. Send estions for reducing the burden to: Director, OPPE			
Certification with Respec	t to Citation of	Data			
Applicant's/Registrant's Name, Address, and Telephone Number United Phosphorus, Inc.; 423 Riverview Plaza, Trenton, NJ 08611; (253) 853-7369	3	EPA Registration Number/File Symbol 70506-93			
Active Ingredient(s) and/or representative test compound(s) Clopyralid		Date September 8, 2005			
General Use Pattem(s) (list all those claimed for this product using 40 CFR Part 158 Terrestrial Food Crop, Terrestrial Nonfood Crop	3)	Product Name Clopyralid Technical			
NOTE: If your product is a 100% repackaging of another purchased EPA-registere submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator)		r all the same uses on your label, you do not need to			
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies ser	nt offers of compensation (the Data Matrix form should			
SECTION I: METHOD OF DATA SUPP	ORT (Check one m	ethod only)			
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under the	g the selective method of support (or cite-all option selective method), and have included with this form a d list of data requirements (the Data Matrix form must be			
SECTION II: GENERAL	OFFER TO PAY				
[Required if using the cite-all method or when using the cite-all option under the selection of the cite-all option under the cite-all option under the cite-all options of the cite-all option under the cite-all options of the					
SECTION III: CERT	IFICATION '				
I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-In response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application souguses.	n addition, if the cite-a at (1) concern the pro is a type of data that ght the initial registrat	all option or cite-all option under the selective method is operties or effects of this product or an identical or would be required to be submitted under the data tion of a product of identical or similar composition and			
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	or reregistration, tha	at I am the original data submitter or that I have obtained			
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.					
I certify that the statements I have made on this form and all attachm knowingly false or misleading statement may be punishable by fine or impriso					
Signature	Date	Typed or Printed Name and Title			

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.



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WASHINGTON, D.C. 20460

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	DATA I	MATRIX			
Date September 8, 2005			EPA Reg No./File Symbol 70506-	Page ( of 5	
Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product Clopyralid Techn			
Ingredient Clopyralid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Specific Data Re	quirements				
830.1550	Product Identity and Composition	45751501 45755601	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.1600	Description of Materials Used to Produce the Product	45751501 45755601	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.1620	Description of Production Process	45751501 45755601	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.1650	Description of Formulation Process				Not required <sup>2</sup>
830.1670	Discussion of Formation of Impurities	45751501 45755601	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.1700	Preliminary Analysis	45751502	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.1750	Certified Limits	45751501 45755601	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.1800	Enforcement Analytical Method	45751502	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.6302	Color	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.6303	Physical State	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
Signature / Name and Title			Date		
Michael Kellogg, Consultant					9/8/05



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	DATA M	ATRIX				
Date September 8, 2005	Date September 8, 2005			EPA Reg No./File Symbol 70506-93		
Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product Clopyralid Technical				
Ingredient Clopyralid				<del></del>		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.6304	Odor	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
830.6314	Oxidation/Reduction: Chemical Incompatibility				Not required <sup>3</sup>	
830.6315	Flammability				Not required <sup>3</sup>	
830.6316	Explodability				Not required <sup>3</sup>	
830.6317	Storage Stability				Not required <sup>3</sup>	
830.6319	Miscibility	<u> </u>			Not required <sup>3</sup>	
830.6320	Corrosion Characteristics				Not required <sup>3</sup>	
830.6321	Dielectric Breakdown Voltage	<u></u>			Not required <sup>3</sup>	
830.7000	рН	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
830.7050	UV/Visible Absorption	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
830.7100	Viscosity				Not required <sup>3</sup>	
830.7200	Melting Point/Melting Range	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
Signature	-		Name and Title		Date	
mental &	ODDAY .		Michael Kellogg, Consultant		9/8/05	



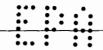
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Date September 8, 2005	ate September 8, 2005			-93	Page 3 of 5
Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Page Product Clopyralid Technical			
Ingredient Clopyralid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7220	Boiling Point/Boiling Range				Not required⁴
830.7300	Density/Relative Density/Bulk Density	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.7370	Dissociation Constants in Water	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
830.7860	Water Solubility, Generator Column Method				See 830.7860
830.7950	Vapor Pressure	45751503 45751504	United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
Signature			Name and Title		Date
neihar	xODOQY		Michael Kellogg, Consultant		9/8/05



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



401 M Street, S.W. WASHINGTON, D.C. 20460

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Date September 8, 2005			EPA Reg No./File Symbol 70506-	93	Page 4 of 5	
Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611			Product Clopyralid Technical			
Ingredient Clopyralid		,				
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY		
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY		
870.2500	Primary Dermal Irritation	Cite-All		PAY		
870.2600	Dermal Sensitization	Cite-All		PAY		
Generic Data Requirement United Phosphorus, Inc. wil	I make offers-to-pay to the following companies on the	e data				
submitters list of March 31,	2005.  Cite-All Method utilized by United Phosphorus,	T	Nufarm Americas Inc.	PAY		
Clopyralid Generic Data Requirements	Inc. for Clopyralid data requirements		Nulaim Americas inc.	FAT		
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Lebanon Seaboard Corporation	PAY		
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Albaugh, Inc.	PAY		
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Dow AgroSciences LLC	PAY		
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Spray Drift Task Force		See endnote	
Signature	Day		Name and Title Michael Kellogg, Consultant		Date 9/8/05	



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



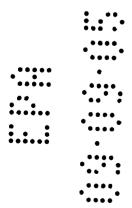
401 M Street, S.W.

WASHINGTON, D.C. 20460

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send the form to this address.						
	DATA M	IATRIX				
Date September 8, 2005	Date September 8, 2005			EPA Reg No./File Symbol 70506-93		
Applicant's/Registrant's Name & Address  United Phosphorus, Inc.  423 Riverview Plaza  Trenton, NJ 08611		Product Clopyralid Technical				
Ingredient Clopyralid		1		Τ		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Outdoor Residential Exposure Task Force		See endnote <sup>6</sup>	
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Agricultural Re-entry Task Force		See endnote <sup>7</sup>	
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		AgValue-Clopyr, LLC		See endnote <sup>8</sup>	
Clopyralid Generic Data Requirements	Cite-All Method utilized by United Phosphorus, Inc. for Clopyralid data requirements		Agricultural Handler Exposure Task Force	PAY		
Signature Mushaul	Dagg		Name and Title Michael Kellogg, Consultant		Date 9/8/05	

#### **Endnotes for Data Matrix for Clopyralid Technical**



<sup>&</sup>lt;sup>1</sup> Data originally submitted by AgValue-Clopyr, LLC, now owned by United Phosphorus, Inc.

<sup>&</sup>lt;sup>2</sup> 830.1650 – Per OPPTS 830.1000, these data are not required for the registration of a technical grade active ingredient. See 830.1620 for production process information.

<sup>&</sup>lt;sup>3</sup> **830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100** – Per OPPTS 830.1000, these data are not required for the registration of a technical grade active ingredient.

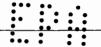
<sup>&</sup>lt;sup>4</sup> **830.7220** – Per OPPTS 830.1000, these data are not required for the registration of Clopyralid Technical because this product is a solid. Please refer to OPPTS 830.7200.

<sup>&</sup>lt;sup>5</sup> United Phosphorus, Inc. is a member of this task force; therefore, no offer-to-pay is required to be submitted.

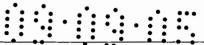
<sup>&</sup>lt;sup>6</sup> United Phosphorus, Inc. is a member of this task force; therefore, no offer-to-pay is required to be submitted.

<sup>&</sup>lt;sup>7</sup> United Phosphorus, Inc. is a member of this task force; therefore, no offer-to-pay is required to be submitted.

United Phosphorus, Inc. owns AgValue-Clopyr, LLC and as such, an offer-to-pay is not being made to AgValue-Clopyr, LLC



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		DATA MATRIX			
Date September 8, 2005			EPA Reg No./File Symbol 70506-	.93	Page / of 5
Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product Clopyralid Technical			
Ingredient Clopyralid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
			United Phosphorus, Inc.	OWN	See endnote
			United Phosphorus, Inc.	OWN	See endnote
					Not required
			United Phosphorus, Inc.	OWN	See endnote
			United Phosphorus, Inc.	OWN	See endnote
			United Phosphorus, Inc.	OWN	See endnote
			United Phosphorus, Inc.	OWN	See endnote
			United Phosphorus, Inc.	OWN	See endnote
			United Phosphorus, Inc.	OWN	See endnote
Signature	$\sim$		Name and Title		Date
without x	WDOYY		Michael Kellogg, Consultant		9/8/05



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Date September 8, 2005	Date September 8, 2005			EPA Reg No./File Symbol 70506-93		
Applicant's/Registrant's Name & Address		Product				
	United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Clopyralid Technical			
Ingredient Clopyralid						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
					Not required <sup>3</sup>	
					Not required <sup>3</sup>	
					Not required <sup>3</sup>	
					Not required <sup>3</sup>	
					Not required <sup>3</sup>	
					Not required <sup>3</sup>	
					Not required <sup>3</sup>	
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
					Not required <sup>3</sup>	
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>	
Signature			Name and Title		Date	
minhal salls	Day		Michael Kellogg, Consultant		9/8/05	

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

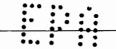
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		DATA MATRIX			
Date September 8, 2005  Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611			EPA Reg No./File Symbol 70506-	Page 3 of 5	
		Product Clopyralid Technical			
Ingredient Clopyralid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
					Not required⁴
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
					See 830.7550
					See 830.7550
			United Phosphorus, Inc.	OWN	See endnote
					See 830.7860
			United Phosphorus, Inc.	OWN	See endnote <sup>1</sup>
				PAY	
				PAY	
Signature			Name and Title		Date
michael &	O(X) save		Michael Kellogg, Consultant		alalar

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**Public File Copy** 



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Date September 8, 2005			EPA Reg No./File Symbol 70506-	Page∠ of 5	
Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		Product  Clopyralid Technical			
ngredient Clopyralid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				PAY	
			Nufarm Americas Inc.	PAY	
			Lebanon Seaboard Corporation	PAY	
			Albaugh, Inc.	PAY	
			Dow AgroSciences LLC	PAY	
			Spray Drift Task Force		See endnot
signature /	200		Name and Title		Date
11:11-11	(11 /20)		Michael Kellogg, Consultant		alalas



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WASHINGTON, D.C. 20460

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	1	DATA MATRIX			
Date September 8, 2005  Applicant's/Registrant's Name & Address  United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611		EPA Reg No./File Symbol 70506-93	Page 5 of 5		
		Product  Clopyralid Technical			
Ingredient Clopyralid					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Outdoor Residential Exposure Task Force		See endnote <sup>6</sup>
			Agricultural Re-entry Task Force		See endnote <sup>7</sup>
			AgValue-Clopyr, LLC		See endnote <sup>8</sup>
			Agricultural Handler Exposure Task Force	PAY	
Signature	Maria		Name and Title Michael Kellogg, Consultant		Date

Please read instructions on reverse before completing form Form Approved, OMB No. 2070-0060, Approval expires 5-31-98 **OPP Identifier Number** Registration **United States** Amendment 274882 **Environmental Protection Agency** X Other Washington, DC 20460 Application for Pesticide - Section I 2. EPA Product Manager 1. Company/Product Number 3. Proposed Classification 70506-93 J. Miller 4. Company/Product (Name) PM# Restricted None United Phosphorus, Inc/Clopyralid Technical 23 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) 5. Name and Address of Applicant (Include ZIP Code) (b)(i), my product is similar or identical in composition and labeling United Phosphorus, Inc. 423 Riverview Plaza Trenton, NJ 08611 EPA Reg No. Check if this is a new address **Product Name** Section - II Amendment - Explain below Final printed labels in response to Agency letter dated NOTIFICATION Resubmission in response to Agency letter dated "Me Too" Application JUL 2 1 2005 Notification - Explain below Other - Explain below Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Notification of changes to label and CSF related to change in company ownership. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA. Section III 1. Material This Product Will be Packaged in: Child-Resistant Packaging Unit Packaging Water Soluble Packaging Type of Container Metal Yes Yes Yes Plastic No No No Glass \*Certification must If "Yes" No. per If "Yes" No. per Paper Unit Packaging wgt. container container be submitted Package wgt Other (Specify) 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of label directions On Label Container On Label accompanying product 6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled Section IV 1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Name Telephone No. (Include Area Code) Title Rebecca A. Clemmer Regulatory Affairs Manager Certification 6. Date Application Received I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. .... I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law 2. Signature 3. Title (Stamped) Regulatory Affairs Manager 4. Typed Name 5. Date Rebecca A. Clemmer July 7, 2005 White - EPA File Copy (Original) EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. Yellow - Applicant Copy

## **AgValue** Clopyralid Technical

ACTIVE INGREDIENT:	
Clopyralid: 3,6-dichloro-2-pyridinecarboxylic acid	96.0%
INERT INGREDIENTS:	4.0%
TOTAL	100.00/

## KEEP OUT OF REACH OF CHILDREN DANGER

-	DANGER
	FIRST AID
If in eyes:	<ul> <li>Hold eye open and rinse slowly with a steady, gentle stream of water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a physician or poison control center immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>DO NOT induce vomiting unless told to do so by poison control center or physician.</li> </ul>
	<ul> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably, mouth-to-mouth, if possible.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If on skin or	Take off contaminated clothing.
clothing:	<ul> <li>Wash skin with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
Note to Physician	Probable mucosal damage may contraindicate the use of gastric lavage.
•	container or label with you when calling a poison control center or doctor,
	gency: spill, leak, fire, exposure or accident, call CHEMTREC at 1-800-

See side panel for additional precautionary statements.

#### Manufactured For:

AgValue Clopyr, LLCUnited Phosphorus, Inc. Visalia, CA 93291423 Riverview Plaza

Trenton, NJ 08611

1-800-247-1557 • www.upi-usa.com

EFA ESt. No.

EPA Reg. No. 75147-370506-93

Net Weight:

NOTIFICATION

JUL 2 1 2005

# PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals DANGER

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Do not get in eyes or on skin and clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

#### **Agricultural Uses**

Asparagus, barley, corn, fallow land, grasses, mint, oats, pasture, rangeland, sugar beets, tree plantations, and wheat. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult AgValue Clopyr, LLCUnited Phosphorus, Inc. for instructions for formulation and other information.

#### Non-Agricultural Uses

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial sites, non-cropland, parks, rights-of-way, and roadsides. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s). Consult AgValue Clopyr, LLCUnited Phosphorus, Inc. for instructions for formulation and other information.

This product must not be formulated into manufacturing-use products or end-use products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

- Do not use on residential turf
- Do not send clippings to a compost facility
- Do not collect grass clippings for mulch or compost
- Applicator must give notice to landowners/property managers to not use grass clippings for composting.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

#### PESTICIDE STORAGE

Store in a cool, dry, well-ventilated area.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

#### CONTAINER DISPOSAL

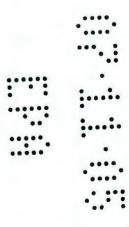
Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

## CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

United Phosphorus, Inc. warrants that at the time of delivery, this product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that the seller will convey title hereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. UNITED PHOSPHORUS, INC. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. BUYER ACKNOWLEDGES THE USE OF ITS OWN INDEPENDENT SKILL AND EXPERTISE IN THE SELECTION AND USE OF THE PRODUCT AND DOES NOT RELY ON ANY ORAL OR WRITTEN STATEMENTS OR REPRESENTATIONS.

Rev. 6/05





## United Phosphorus, Inc.

423 Riverview Plaza Trenton, NJ 08611 (609) 392-8200 x 18 (phone) (609) 392-0808 (fax) Rebecca A. Clemmer Regulatory Affairs Manager

July 7, 2005

Joanne Miller (PM 23)
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protections Agency
1801 Bell Street
Arlington, VA 22202

Re: Submission of Revised Labeling and Confidential Statements of Formula for Clopyralid Technical (EPA Reg. No. 70506-93)

Oryzalin Technical (EPA Reg. No. 70506-95)

Etho Tech (EPA Reg. No. 70506-105)

Dear Ms. Miller:

In connection with the recent transfer of registrations from AgValue to United Phosphorus, UPI is submitting the attached Notifications to accomplish these actions for the subject products:

- remove "AgValue" from the product names;
- add CHEMTREC contact information to the main panel;
- update all AgValue information to United Phosphorus; and
- add warranty language.

In support of the changes, enclosed please find:

- one copy of each label, marked to show changes, and
- EPA form 8570-1 for each product.

Also enclosed for your files is a copy of a Confidential Statement of Formula for each of the products. These CSFs are the most recently approved versions already in Agency files, with the only changes being the company name and EPA Registration Number.

Please contact me if you have any questions.

Very truly yours,

Rebecca A. Clemmer relemmer@upi-usa.com



#### United Phosphorus, Inc.

423 Riverview Plaza Trenton, NJ 08611 (609) 392-8200 (phone) (609) 392-0808 (fax) Ann M. Tillman Technical Director

December 14, 2004

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agent for United Phosphorus, Inc. (EPA Company Number 70506), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

In addition, United Phosphorus Inc. (UPI) recently purchased AgValue, Inc. (and its subsidiaries) and UPI is currently in the process of transferring current and pending registrations to UPI. Until the transfer is complete, Pyxis Regulatory Consulting, Inc. is also authorized to act as agent for AgValue, Inc. (EPA Company Number 73917) and its subsidiaries, including but not limited to AgValue-Bromacil, LLC (EPA Company Number 80824); AgValue-Clopyr, LLC (EPA Company Number 75147); AgValue-DP, LLC (EPA Company Number 75240); AgValue-Etho, LLC (EPA Company Number 75522); AgValue-Metri, LLC (EPA Company Number 79604); AgValue-Oryza, LLC (EPA Company Number 75722); AgValue-Pronamide, LLC (EPA Company Number 80825); and AgValue-Propargite, LLC (EPA Company Number 81994), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Ann M. Tillman, Ph.D. Technical Director

am hallen

United Phosphorus, Inc.

cc: J. Kay, Pyxis Regulatory Consulting, Inc.



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

April 28, 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MS. ANN TILLMAN
UNITED PHOSPHORUS INC
423 RIVERVIEW PLAZA
TRENTON, NJ 08611

Dear Ms. Tillman:

Subject:

Transfer of Pesticide Registrations and Data From Company Number 75147 to

Company Number 70506

Pursuant to your request in your letter and transfer agreement of November 23, 2004 and subsequent information received on January 26, 2005, we have approved the transfer of the following registrations and data from AGVALUE-CLOPYR, LLC, company number 75147 to UNITED PHOSPHORUS INC, company number 70506.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
AGVALUE CLOPYRALID TECHNICAL	75147-3	70506-93
AGVALUE CLOPYRALID AG HERBICIDE	75147-4	70506-94

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into

supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated November 23, 2004 and subsequent information received on January 26, 2005 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date UNITED PHOSPHORUS INC will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Evelyn Alston at (703) 305-5058.

Sincerely,

Kathryn S. Bouve, Chief
Information Services Branch

Information Resources & Services Div. (7504C)

cc: N. BUSHAN MANDAVA MANDAVA ASSOCIATES, AGENT FOR

AGVALUE-CLOPYR, LLC 1730 M STREET, N.W., SUITE 906 WASHINGTON, DC 20036-4510

#### PYXIS REGULATORY CONSULTING, INC.

11324 17<sup>th</sup> Ave. Ct. NW Gig Harbor, WA 98332

Phone: 253-853-7369 Fax: 253-853-5516 Email: www.PyxisRC.com

June 21, 2004

#### **COURIER DELIVERY**

Joanne Miller (PM23)
Document Processing Desk (FNL LBL)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: AgValue-Clopyr, LLC – AgValue Clopyralid Technical (EPA Reg. No. 75147-3) Submission of Final Labeling per the Agency Letter dated May 1, 2003

Dear Ms. Miller,

On behalf of AgValue-Clopyr, LLC please find the enclosed final product labeling in response to the Agency letter dated May 1, 2003. In support of this submission, please find the following:

- 1. Application for Pesticide Registration (EPA Form 8570-1)
- 2. One (1) copy of the AgValue Clopyralid Technical final label
- 3. Letter of Authorization

Please feel free to call me if you have any questions or need any additional information.

Sincerely

Michael Kellogg

**Enclosures** 

cc: Brian Heinze; AgValue-Clopyr, LLC

		Inited Cares				Bogist-	ation	OPP Identifier Number
<b>\$EPA</b>	Environmenta	United States	n Agency			Registra		
<b>VLIM</b>		ington, DC 204			V	Amend Other	ment	
		Application	on for Pestic	ide - Sec	tion			
1. Company/Product Number	er		1	Product Mar			3. Pi	oposed Classification
75147-3			J. Mill	er			[v	None Restricted
<ol> <li>Company/Product (Name AgValue-Clopyr, LLC /</li> </ol>		d Technical	PM#		23	·		J []
<ol> <li>Name and Address of Ap AgValue-Clopyr, LLC c/o Pyxis Regulatory Co</li> </ol>	onsulting, Inc.	ode)	1					FIFRA Section 3(c)(3) imposition and labeling
11324 17th Ave. Ct. NV Gig Harbor, WA 98332	V		1	Reg. No		<del> </del>		
Check if thi	s is a new address		Produ	uct Name				
			Section -	11				
Amendment - Explai	n below.			Final printe		ls in repsons	se to Ma	ay 1, 2003
Resubmission in res	oanse to Agency letter	dated		"Me Too"			*	
Notification - Explain	below.			Other - Exp	olain be	olow.		
1. Material This Product Wi	ll Be Packaged In:		Section - I	111				
Child-Resistant Packaging	Unit Packaging		Water Soluble F	Packaging		2. Type of	Container	
Yes	Yes		Yes				Metal	
No	No		No				Plastic Glass	
Pertification must be submitted	If "Yes" Unit Packaging wgt	No. per . container	If "Yes" Package wgt	No. per containe	or		Paper	Specify)
3. Location of Net Contents	Information	4. Size(s) Ret	ail Container	<u> </u>	5. Lo	cation of La	bel Direction	ons
	Container					On Labelin	g accompany	ing product
6. Manner in Which Label is	Affixed to Product	Lithog Paper Stenci	raph glued led	Othe	·r			
			Section - I	V				
1. Contact Point (Complete	items directly below	for identificatio	n of individuel to b	e contacted,	if nec	essary, to p	rocess this	application.)
Name Michael Kellogg			Title Agent					e No. (Include Area Code) 53-7369
	ements I have made or ny knowlinglly false or Iaw.		all attachments th					6. Date Application Received  (Stamped)
2. Signature  Minhay	sally,		3. Title Agent					
4. Typed Name			5. Date	1 .				••••
Michael Kellogg			,	1				

#### AgValue Clopyralid Technical

#### **ACTIVE INGREDIENT:**

Clopyralid:	3,6-dichloro-2-pyridinecarboxylic acid	96.0%
INERT ING	REDIENTS:	4.0%

TOTAL ......100.0%

#### KEEP OUT OF REACH OF CHILDREN DANGER

	DANGER
	FIRST AID
If in eyes:	<ul> <li>Hold eye open and rinse slowly with a steady, gentle stream of water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a physician or poison control center immediately for treatment advice.</li> <li>Have person sip a glass of water if able to swallow.</li> <li>DO NOT induce vomiting unless told to do so by poison control center or physician.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably, mouth-to-mouth, if possible.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If on skin or clothing:	<ul> <li>Take off contaminated clothing.</li> <li>Wash skin with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
Note to Physician:	Probable mucosal damage may contraindicate the use of gastric

lavage.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Manofactured For: AgValue-Clogyr, LLC Visalia, CA 93291 in Accordance with PR Notice 82-2 Pased on Draft Labeling Dated

Net Weight: 44 Lbs. (20 KG)



## PRECAUTIONARY STATEMENTS Hazard to Humans and Domestic Animals DANGER

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin or inhaled. Do not get in eyes or on skin and clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

#### **Agricultural Uses**

Asparagus, barley, corn, fallow land, grasses, mint, oats, pasture, rangeland, sugar beets, tree plantations, and wheat. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult AgValue-Clopyr, LLC for instructions for formulation and other information.

#### Non-Agricultural Uses

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial sites, non-cropland, parks, rights-of-way, and roadsides. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such uses(s). Consult AgValue-Clopyr, LLC for instructions for formulation and other information.

This product must not be formulated into manufacturing-use products or end-use products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

Do not use on residential turf

Do not send clippings to a compost facility

Do not collect grass clippings for mulch or compost

Applicator must give notice to landowners/property managers to not use grass clippings for composting.

#### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

#### PESTICIDE STORAGE

Store in a cool, dry, well-ventilated area.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

#### CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.



1124 North Chinowth Street • Visalia, California 93291

Phone: 559/627-6956 • Fax: 559/627-6962 • Toll Free: 866/511-3171 • www.agvalue.net

April 12, 2004

To Whom It May Concern:

RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized as agents for AgValue-Clopyr, LLC (EPA Company Number 75147) before the U.S. Euvironmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

AGVALUE

Sincerely,

Brian Heinze

President/CEO

ec: Pyxis Regulatory Consulting, Inc.



U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (7505C) 401 "M" St., S.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

x Registration
Reregistration
(under FIFRA, as amended)

EPA Reg. Number:

Date of Issuance:

75147-3

MAY 1 2003

Term of Issuance:
Conditional

Name of Pesticide Product:

AgValue Clopyralid Technical

Name and Address of Registrant (include ZIP Code):

AgValue-Clopyr, LLC 1124 N. Chinowth Street Visalia, CA 93291

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration/ reregistration of your product when the Agency requires all registrants of similar products to submit data.
- 2. Make the following label changes listed below before you release the product for shipment:
  - a. Add the phrase, "EPA Reg. No.75147-3".
  - b. In the first bullet on the second page correct the spelling of "not".
  - c. The net contents must be in English Units. According to our calculations 44 lbs. The Metric unit may follow the English Unit. Refer to 40 CFR 156.10(d).
- 3. Submit the results of the one year storage stability and corrosion characteristics studies upon completion.

vanne I Miller

Signature of Approving Official:

Date

MAY 1 2003

page 2 EPA Reg. No.75147-3

4. Submit one (1) copy of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Joanne I. Miller
Product Manager (23)
Herbicide Branch
Registration Division (7505C)

### AGVALUE CLOPYRALID TECHNICAL

Clopyralid: 3,6-dichloro-2-pyridinecarboxylic acid 96	^ 9
cropyratid: 5,0 dremoro-z pyridinecarboxyric acid 96	. 01
INERT INGREDIENTS: 4	
TOTAL 100	. 0 9

# KEEP OUT OF REACH OF CHILDREN DANGER

	FIRST AID
If in eyes:	<ul> <li>Hold eye open and rinse slowly with a steady, gentle stream of water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If swallowed:	<ul> <li>Call a physician or poison control center immediately for treatment advice</li> <li>Have person sip a glass of water if able to swallow.</li> <li>DO NOT induce vomiting unless told to do so by poison control center or physician.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably, mouth-to-mouth, if possible.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
If on skin or : clothing	<ul> <li>Take off contaminated clothing.</li> <li>Wash skin with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>
Note to Physician lavage.	: Probable mucosal damage may contraindicate the use of gastric
Have the product doctor, or going	container or label with you when calling a poison control center or for treatment

See side panel for additional precautionary statements.

Net Contents: 20 KG

EPA Est. No. EPA Reg. No. 75147Manufactured For: with COMMENTS:
AgValue-Clopyr, LLdn EPA Letter Dateds

Visalia, CA 93291 MAY 1 2003

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No.

(Side Panel)

#### PRECAUTIONARY STATEMENTS

## Hazard to Humans and Domestic Animals DANGER

Corrosive. Causes irreversible eye damage. Harmful is absorbed through skin or inhaled. Do not get in eyes or on skin and clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

#### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board of Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

### Agricultural Uses

Asparagus, barley, corn, fallow land, grasses, mint, oats, pasture, rangeland, sugar beets, tree plantations, and wheat. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult AgValue-Clopyr, LLC for instructions for formulation and other information.

### Non-Agricultural Uses

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial sites, non-cropland, parks, rights-of-way, and roadsides. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult AgValue-Clopyr, LLC for instructions for formulation and other information.

This product must not be formulated into manufacturing-use products or end-use herbicide products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

- Do no use on residential turf
- Do not send clippings to a compost facility
- Do not collect grass clippings for mulch or compost
- Applicator must give notice to landowners/property managers to not use grass clippings for composting.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry, well-ventilated area.

### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

### CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

# 14627

DP BARCODE: D288008

CASE: 067389 DATA PACKAGE RECORD SUBMISSION: S628339 BEAN SHEET

BEAN SHEET

DATE: 01/27/03

Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 166 RESB NEW PRO-OC-MIN CHG

RANKING : 10 POINTS ()

CHEMICALS: 117403 Clopyralid (ANSI)

96.0000%

ID#: 075147-G AGVALUE CLOPYRALID TECHNICAL

COMPANY: 075147 AGVALUE-CLOPYR, LLC

PRODUCT MANAGER: 23 JOANNE MILLER 703-305-6224 ROOM: CM2 237 703-305-7391 ROOM: CM2 PM TEAM REVIEWER: JAMES STONE

RECEIVED DATE: 01/21/03 DUE OUT DATE: 07/20/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 288008 EXPEDITE: N DATE SENT: 01/27/03 DATE RET.: / /

CHEMICAL: 117403 Clopyralid (ANSI)

DP TYPE: 001 Submission Related Data Package

5-6-03 CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 06/16/03 DIV : RD 1 1 NEGOT DATE: / / / / BRAN: TRB PROJ DATE:

SECT: CHEM REVR: S.B. math 9/21/02

\* \* \* DATA REVIEW INSTRUCTIONS \* \*

Review revised CSF and response to Shyam Mathur's review dated 12-27-02.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL DATE OUT: 22/ APR / 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI / MP [] EP [X]

DP BARCODE No.: D288008 File Symbol No.: 75147-G PRODUCT NAME: AGVALUE Clopyralid

**Technical** 

COMPANY: AGVALUE-CLOPYR, LLC PCC: 117403

FOOD USE [X] INTEGRATED FORMULATION [X]

FROM:

Shyam Mathur, Team Leader

Product Chemistry Team

Technical Review Branch/RD (7505C)

TO:

Joanne Miller / James Stone, PM 23

Herbicide Branch/RD(7505C)

### INTRODUCTION:

The product chemistry data for the proposed technical was reviewed previously (PCR dated 12-27-02, D285622). The registrant was advised to correct the CSF for basic formulation, submit data on one year storage stability (830.6317) and corrosion characteristics (830.6320) studies. The registrant was also informed to explain the significant difference in the values of density for the proposed technical (75147-G) and the registered technical (62719-80). The two products were determined to be substantially similar from the product chemistry view point. The applicant is requesting the conditional registration for the proposed technical.

The registrant responded on January 15, 2003 and provided all the required information. The TRB has been asked to evaluate the submitted data.

### **FINDINGS & CONCLUSIONS:**

- 1. The revised CSF for basic formulation (dated 01-15-03) is filled out correctly and completely. The nominal concentration of the active ingredient Clopyralid (96%) concurs with the product label claim nominal concentration. It is in compliance with PR Notice 91-2. The revised CSF for basic formulation is acceptable.
- 2. The registrant has stated that the studies corresponding to guideline reference 830.6317 (one year storage stability) and 830.6320 (Corrosion characteristics) will be started once the conditional registration is approved for the product.
- 3. The registrant also explained the difference in the density values for the proposed and registered technical. The Agency agrees with the explanation provided.
- 4. All other product chemistry data for the proposed technical satisfy the product chemistry data requirements of 40CFR158.150 to 150.190.

### MANDAVA ASSOCIATES

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-Mail: mandava@compuserve.com

### HAND DELIVERED

Ms. Joanne I. Miller Product Manager 23 Herbicide Branch Registration Division (7505C) U.S. Environmental Protection Agency Washington, DC 20460 January 15, 2003

SUBJECT:

ME-TOO Application For Registration of AgValue CLOPYRALID

TECHNICAL

Active Ingredient: Clopyralid EPA File Symbol: 75147-G

Response to Your Letter Dated January 7, 2003

Dear Ms. Miller:

This letter is in response to your January 7, 2003 letter informing us that the application for AgValue Clopyralid Technical (EPA File Symbol: 75147-G) is incomplete because of some deficiencies identified in your letter.

In this letter, we have addressed and/or corrected the deficiencies as noted below:

### 1. Product Chemistry Issues:

a. There is a significant difference in the density values of the proposed product [31.2 lbs/cu.ft] and the registered product. Verify the accuracy of the measurement of the density of Clopyralid produced by

<u>Response</u>: The density of the AgValue Clopyralid Technical was found to be 0.501 g/mL at 20°C (which is equivalent to 31.2 lbs/ft³). The registered product (Clopyralid by Dow AgroSciences) has a relative density of 1.575 at 20°C and a bulk density of 0.46 g/mL at 25°C. [See Dow AgroSciences Clopyralid, a North American Technical Profile. Source: http://wric.ucdavis.edu/yst/manage/ClopTechProfile.pdf).

The reported value is 1.57 at 20°C (Source: Pesticide Manual, 10th Edition, 2000).

The method that was used for density determination of the proposed product (see Page 21 of 36, Volume 3B; MRID #45751504) involves the measurement of the weights of the test substance at two different specified marks ("0" and "24") in Le Chatelier density bottle. The procedure consists of three steps:

Step 1: Measurement of the volume of the bottle up to mark "0" and mark "24" with water (whose density is known).

Step 2: Measurement of the weight of the test substance in that known volume up to mark "0" and "24" (see Step 1).

Step 3: Calculation of density using the volume (from Step 1) and weight of the test substance (occupies to mark "0" and "24").

The data presented on Page 21 of 36 in Volume 3B (MRID #45751504) showed that the density of the test substance is 0.501 g/mL.

In order to verify the value obtained from the above-mentioned method, we have determined the bulk density by measuring the weight of the test substance for a known volume. [Weighing the test substance that occupies 100 ml of the graduated (measuring) cylinder.] The bulk density of the test substance was found to be 0.47 g/mL at ambient temperature.

As shown above, Dow AgroSciences reported the bulk density of clopyralid technical is 0.46 g/mL at 25°C. The density of AgValue Clopyralid Technical is 0.501 g/mL at 20°C. In other words, what we measured for the subject product is the bulk density (using the Le Chatelier density bottle) which is close to the value reported by Dow AgroSciences.

Additional information on the usage of density, relative density and bulk density is provided in Attachment 1.

- b. Submit a updated Confidential Statement of Formula with the following corrections:
  - i. The lower certified limit of the first impurity listed on the CSF is incorrect and must be deleted from the CSF.

<u>Response</u>: In the revised Confidential Statement of Formula (CSF), we deleted the lower certified limit for the first impurity. The amended CSF is enclosed with this letter.

ii. Specify the Total Weight in Box 17.

Response: The Total Weight in Box 17 is entered as shown in the revised CSF.

iii. The % by weight column 13.b. must total 100%.

Response: In the revised CSF, the % by weight in column 13.b now totals 100% as shown in the revised CSF.

c. You must conduct one year storage stability [830.6317] and corrosion characteristics [830.6320] studies under warehouse conditions in commercial containers. The results of these studies must be submitted to the Agency upon completion.

<u>Response</u>: The storage stability [830.6317] and corrosion characteristics [830.6320] studies will be initiated after the registration for the subject product is granted and a report (containing the results) will be submitted to EPA within 2 years. Please grant the registration so that the company will initiate these studies.

### 2. <u>Labeling Issues</u>:

The applicant claimed that the subject product (AgValue CLOPYRALID TECHNICAL, EPA File Symbol: 75147-G) is substantially similar to LONTREL T Technical which was originally registered by Dow Chemical Company (EPA Reg. No.: 464-613). LONTREL T Technical was subsequently transferred to Dow AgroSciences (Reg. No.: 62719-80). The current label for LONTREL T Technical was approved by EPA on September 27, 2002.

When we prepared the registration application for the subject product, we used the LONTREL T Technical label approved by EPA on February 12, 1998. This was the label that was available to us when we submitted our registration application for AgValue CLOPYRALID TECHNICAL (EPA Receipt Date: September 3, 2002).

We noticed that the Agency used the LONTREL T Technical label approved on September 27, 2002 for suggesting corrections to proposed product label. We have made all the recommended changes in the draft label for AgValue CLOPYRALID TECHNICAL (EPA File Symbol: 75147-G). We have also included in the revised label additional information on "Agricultural Uses" and "Non-agricultural Uses" sections based on the information presented in LONTREL T Technical. A revised draft label (five copies) for the subject product is enclosed.

We have provided our responses to your suggestions and corrections to draft label as noted below:

Submit five draft labels with the following corrections:

a. If all of the Precautionary Statements do not appear on the front panel, add a referral statement similar to the following:

See side panel for additional precautionary statements.

<u>Response</u>: As you suggested, we have included a statement on the amended draft label. We are submitting copies of amended draft label for your approval.

b. At the beginning of the Hazards to Humans section add "Corrosive".

<u>Response</u>: As you suggested, we have added the phrase "corrosive" at the beginning of the Hazards to Humans section.

c. In the Manufacturing Use Only section delete "trees", "industrial sites", non-cropland", "rights-of-way" and "turf". Delete the comma "," between sugar and beets.

<u>Response</u>: As per your suggestion, we have deleted "trees", "industrial sites", non-cropland", "rights-of-way" and "turf" and also the comma "," between sugar and beets in the Manufacturing Use Only section. Please note that we have replaced Manufacturing Use Only section with Agricultural Use section consistent with the information in LONTREL T Technical label (EPA approval date: September 27, 2002).

d. If you intend this product to be used to manufacture herbicides for non-agricultural uses, add a section similar to the following:

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial sites, non-cropland, parks, rights-of-way, and roadsides.

This product must not be formulated into manufacturing-use products or end-use herbicide products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

- Do no use on residential turf
- Do not send clippings to a compost facility
- Do not collect grass clippings for mulch or compost
- Applicator must give notice to landowners/property managers to not use grass clippings for composting.

<u>Response</u>: The amended draft label contains all the suggested changes. We have created "Non-agricultural Use" section and included the information in this section. We have also added other information to this section consistent with the LONTREL T Technical label (EPA approval date: September 27, 2002).

We have enclosed five copies of the revised draft label for AgValue CLOPYRALID TECHNICAL (EPA File Symbol: 75147-G) for your review and approval.

Since all the above-mentioned issues (product chemistry and labeling) are now resolved/or addressed satisfactorily, we request you to grant the registration for the subject product.

Thanks for your ready cooperation.

Sincerely,

N. Bhushan Mandeve

N. Bhushan Mandava, Ph.D., RAC Agent for AgValue, Inc.

Enclosure

cc: Brian Heinze

### COPY OF PAGE 21 OF 36 FROM VOLUME 3B (MRID #45751504)

Page 21 of 36

### DENSITY, BULK DENSITY, OR SPECIFIC GRAVITY

### **Objective**

The objective of this portion of the study was to determine the bulk density of the test substance, Clopyralid Technical, in accordance with Product Properties Test Guidelines, Series 830, Subsection 7300 of the United States Environmental Protection Agency Office of Prevention, Pesticides, and Toxic Substances.

### Procedures

Density was determined at 20°C according to the methods in the Annual Book of ASTM Standards, Designations D941-88, D792-86, D1480-86, and D1217-86; and in the OECD Guidelines for the Testing of Chemicals, Volume 1, Section 1, No. 109 (Adopted 12 May 1981) Density of Liquids and Solids. An empty Le Châtelier density bottle was weighed in order to determine a weight when empty. The volume of the bottle to the "0" and "24" marks were determined using deionized water and the density of water constant at 20°C. For each of two trials, the bottle was filled with test substance to mark "0" and weighed. Additional test substance was added to fill the bottle to the "24" mark, and the bottle was weighed. Between fillings, the bottle was rinsed with deionized water and acetone and dried completely in an approximately 80°C oven. The bottle and water, or test substance, were allowed to equilibrate to 20°C by allowing the bottle to sit for approximately 10 minutes prior to any weighing.

The weight of the empty bottle was subtracted from the weight of the bottle with the test substance to the "0" mark. In addition, the weight of the empty bottle was subtracted from the weight with the test substance at the "24" mark. The density was calculated from the mean of the bottle weights.

#### Resuits

The average density of Clopyralid Technical was determined to be 0.501 g/mL.

Table 11: Density, Bulk Density or Specific Gravity Results

	Calibration with water					Bottle wights (g)			
	Bottle Weights (g)			Volume <sup>1</sup>		with Test Stubstance		Densite <sup>2</sup>	
基本	Empty	Mark	Mark "24"	Mark "0"	Mark "24"	Mark "0"	Mark "24"	Mark "0"	Mark "24"
Trial 1	141.6	394.7	417.7	253.6	276.6	270.3	280.5	0.50758	0.50217
Trail 2	141.6	394.7	417.7	253.6	276.6	268.3	278.8	0.49969	0.49603
1000	1 1 1	EN PALLAN	3. 6	11/13/20	Avera	ge Density	(g/mL)	0.50488	0.49786
		Taraba .			Combi	ned Avera	ge Density	(g/mL)	0.50137

### Notes:

<sup>1</sup>Calibration of Bottle Volume (H<sub>2</sub>O)

Volume = Wt. with water - Wt. Empty

Density of water at 20°C

<sup>2</sup>Density Formula (Test Substance)

Density = Wt. with TS – Wt. empty

Volume of bottle

### **ATTACHMENT 1**

### Clarification on the Usage of Density, Relative Density and Bulk Density

Density is defined as the mass per unit volume of a substance. It must be expressed with the units stated. It refers only to the actual volume occupied by the substance. For solid substances with irregular shapes, this usually involves weighing the solid, filling in the irregular spaces with liquid –usually water – to a known volume and weighing, then filling the same volume with only the liquid and weighing. The weight of liquid occupying the same volume as the solid can then be easily calculated. If the density of the liquid is known, the volume of the liquid, and thereby of the solid, can be calculated by dividing the weight of the liquid by its density. Obviously, this only works if the solid does not dissolve in the liquid.

Since water is the liquid most commonly used, and since its density is well known, relative density, or specific gravity, has become a convenient means of expressing the same property. It is defined as the ratio of the density of a substance at a specific temperature to the density of water at a specific temperature. Since it is a ratio, there are no units, but the temperatures must be specified to be exact.

Density or relative density can be determined on finely divided solids, provided the solid is not soluble and provided that it can be thoroughly wetted by the liquid, so that there are no errors due to air bubbles.

Bulk density refers to the mass of a particulate solid that can fill a unit volume. It is determined simply by weighing the amount of the substance that can be put into a container of known volume. Methods are available that prescribe techniques to obtain reproducible results either as "free pouring" bulk density or as "tap" densities. In either case the bulk density is a measure of how closely the particles of the substance tend to pack. It is affected by the shape and size of the particles. It is necessarily a lower number that the density or relative density. It is useful for predicting what size packaging will be needed for a given weight of the solid.

### ATTACHMENT 1 (cont.)

<u>Further Explanation</u>: Based on the above description, we wish to give further explanation to different density determinations.

In general, there are two types of density determinations:

### A. Bulk density (with 2 subcategories)

- 1. <u>Free-pour density</u>: This is a density obtained by freely pouring the test material into cylinder of known volume. No attempt is made to eliminate clumps of test material (TM) or pockets of air. A crude experiment for clopyralid yielded a free-pour density of 0.27 g/mL.
- 2. <u>Tap density (also called bulk density)</u>: This is very similar to the free-pour density in design; however, the measuring cylinder/container is tapped on a hard surface to collapse the TM. Clumps and pockets are eliminated.

### B. Relative density

The test material is placed in a cylinder and water or appropriate solvent is added. Water takes up all the space between particles. When the density is calculated, the volume used reflects that of perfectly packed test material.

In theory, this would be identical to the volume of the test material if it were melted and cooled into 1 perfect crystal.

As a result, the relative density is normally much greater than the bulk density.

### SUBMISSION TRACKING RECORD

BAR CODE 5628339	ID NUMBER_	75147-6
ACTION CODE 166	РМ 23	
TEAM REVIEWER JUN		
DATE ON APPLICATION 1/5/0	13_	
EPA RECEIVED DATE 1 12( 1 03	3	
PM RECEIVED DATE ( 124, 03		
SPECIAL INSTRUCTIONS:		
FINAL ACTION		
RESPONSE CODE	RESPONSE DATE _	

### MANDAVA ASSOCIATES

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-Mail: mandava@compuserve.com

### **HAND DELIVERED**

February 12, 2003

Ms. Joanne I. Miller Product Manager 23 Herbicide Branch Registration Division (7505C) U.S. Environmental Protection Agency Washington, DC 20460

SUBJECT: EXPEDITED REQUEST FOR REGISTRATION APPLICATIONS

CLOPYRALID TECHNICAL (EPA File Symbol: 75147-G) CLOPYR AG HERBICIDE (EPA File Symbol: 75147-U)

### Dear Ms. Miller:

On behalf of AgValue-Clopyr, LLC, we are requesting the Agency to expedite the registration applications for Clopyralid Technical (EPA File Symbol: 75147-G) and Clopyr AG Herbicide (EPA File Symbol: 75147-U) on the basis that the registrations of these products will serve the Public Good Cause and also will meet the FQPA goals.

### Background Information:

On behalf of AgValue-Clopyr, LLC, we submitted six applications for the registration of the following products:

	Product Name	EPA File Symbol	TRB REDREW Due
1)	Clopyralid Technical	75147-G	5/6/03
2)	Clopyr AG Herbicide	75147-U	517/03
3)	Clopyralid IVM	75147-A	••••
4)	Clopyralid BRUSH	75147-E	
5)	Clopyr-D	75147-R	
6)	Clopyr-M	75147-L	
		de .	••••
			•
		4921BM	••••

We submitted the registration applications (dated August 28, 2003) for the above products and the Agency reviewed the applications under fast track because they are ME-TOO applications. Subsequently, we received comments from the Agency regarding the product chemistry and labeling for these products. In our responses, we addressed and/or corrected the deficiencies identified in your letters. We have also submitted additional data for some products as required by the Agency.

In our February 3, 2003 meeting with the Agency officials, we discussed all the comments on these products. Based on the discussions at this meeting, it is our understanding that all the issues regarding the product chemistry and labeling are resolved. Therefore, we have satisfied the Agency by providing all the requested information.

### Expedite Request ONLY for Two Products

Clopyralid Technical (EPA File Symbol: 75147-G) and — Due from TRB 5/6 Clopyr AG Herbicide (EPA File Symbol: 75147-U) — Due from TRB 5/7

This letter is to specifically request you to expedite the review only for two products, Clopyralid Technical (EPA File Symbol: 75147-G) and Clopyr AG Herbicide (EPA File Symbol: 75147-U) so that the registrations are issued expeditiously. The Agency may take its normal time for the issuance of the registrations for other four products.

### Clopyralid Technical (EPA File Symbol: 75147-G)

In our January 15, 2003 letter to you, we addressed and/or corrected all the deficiencies identified in your January 7, 2003 letter. Our understanding, based on February 3, 2002 meeting, is that all the product chemistry issues are resolved to the satisfaction of the Agency. There is NO additional product chemistry data submitted because it was not required. All the required changes in labeling were made as requested by you. We believe that no additional time and/or resources are needed to review our response (dated January 15, 2003).

Our understanding is that the Agency follows the standard procedures and time frames for document transmittals and reviews - including for Technical Review Branch (TRB) to receive and review our January 15, 2003 response, and send its recommendation to Product Manager, so that PM will approve the registration. We are requesting you to expedite this review process so that you can grant the registration for Clopyralid Technical.

Ms. Joanne I. Miller (PM 23) February 12, 2003 Page 3

### Clopyr AG Herbicide (EPA File Symbol: 75147-U)

In our January 24, 2003 letter to you, we addressed and/or corrected all the deficiencies identified in your January 23, 2003 letter. Our understanding, based on February 3, 2003 meeting, is that all the product chemistry issues are resolved to the satisfaction of the Agency. There is no additional product chemistry data submitted because it was not required. All the required changes in labeling were made as requested by you. We believe that no additional time and/or resources are needed to review our response (dated January 24, 2003).

It is our understanding that the Agency follows the standard procedures and time frames for document transmittals and reviews - including for TRB to receive and review our January 24, 2003 response, and send its recommendation to Product Manager, so that PM will approve the registration. We are requesting you to expedite this review process so that you can issue the registration for Clopyr AG Herbicide.

Why are we requesting you to expedite the registrations?

We need to import Clopyralid Technical (EPA File Symbol: 75147-G) for 2003 growing season which will begin in April. We will need about a month to bring the product into the U.S. We will also need sufficient time to produce Clopyr AG Herbicide (EPA File Symbol: 75147-U) and to make it available to growers through normal distribution channels.

In order to meet these time lines, we are requesting the Agency to grant the registrations expeditiously.

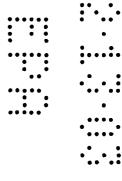
Why are we requesting you to expedite registrations only for two products?

Clopyralid Technical (EPA File Symbol: 75147-G) is the source material and it is required for producing the end-use product(s) including Clopyr AG Herbicide (EPA File Symbol: 75147-U). We are going to use this formulated product (Clopyr AG Herbicide) on sugar beets which is a minor use crop.

The Agency can take its usually required time to take action on other four products (see above for product details).

What is the basis for expedited request?

The bases for expedited request are the following:



### 1) Public Good

The EPA grants expedited registrations in the interest of Public Good. We have received support from sugar beet growers associations and also individual growers demonstrating the need for clopyralid as an alternative source. Availability of clopyralid to grower community helps to insure the high quality of sugar beet crop and to reduce the pressure from weeds thus increasing the crop productivity. In our opinion, making clopyralid available to sugar beet growers is a Public Good Cause.

We have enclosed copies of four letters from sugar beet growers and their associations supporting our request for expedited registrations for clopyralid.

[We will forward the original letters under separate cover].

### 2) Support Registrations for Minor Crop

Our understanding of Minor Use of a pesticide is that it is applied on a commercial agricultural crop or a site to protect health when the crop is a minor crop. Sugar beet is considered as a minor crop. Among several incentives the Agency offers to registrants under FQPA is an "Expedite Registration". This is because there are not many alternative sources for pesticides for use on minor crops and the Agency recognizes the need for pesticides for minor use crops. In order to encourage the registrants, the Agency registers pesticides on a priority basis.

On the basis of the above justification, we request the Agency to grant our request for expedited registrations for the subject products.

Thanks for your ready cooperation.

Sincerely,

N. Bhushan Mandava, Ph.D., RAC Agent for AgValue-Clopyr, LLC

N. Bhushan Mander

Enclosure cc: Brian Heinze

### MANDAVA ASSOCIATES

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512
Telephone: (202)-223-1424/1747 · Fax: (202)-223-0141 · E-MAIL: Mandava@compuserve.com

### NOTE TO MS. JOANNE I. MILLER PRODUCT MANAGER 23

February 12, 2003

We have enclosed copies of the following letters in support of Expedited Registrations for Clopyralid Technical (EPA File No.: 75147-G) and Clopyr AG Herbicide (EPA File Symbol: 75147-U):

- 1) Mike Hofer, Southern Minnesota Beet Sugar Cooperative
- 2) Robert Busch, Nebraska Sugarbeet Growers Association
- 3) Allan Cattanach, American Crystal Sugar Company
- 4) Kevin Martin, Sugarbeet grower

We will forward the original letters under separate cover.

Bhushan Mandava

Bhushen Mandav



February 12, 2003

Ms. Marcia E Mulky
Director
Office of Pesticide Programs
US Environmental Protection Agency
Washington, DC 20460

Dear Ms. Mulky:

I am an agricultural consultant for Southern Minnesota Beet Sugar Cooperative. I work for several sugarbeet farmers and help them address different production problems including weeds, diseases, and insects. Over the past several years, weeds have continued to increase in pressure and increase in the number of species we have to control each year. A key component of control, is the use of post emergent herbicides. Without excellent timing of postemergent herbicides our weed control is very poor. Due to sugarbeets being a relatively small crop the basic chemical manufacturers try to produce just enough herbicide so that they do not carryover much product. As a result of this practice, combined with the ever evolving weed spectrum, we are running into supply blocks in the clopyralid channel, and our growers are missing critical timeframes for there postemergent sprays. This leads to poor weed control, which in turn costs our growers over a million dollars each year. Clopyralid is one of the herbicides with this problem. Several growers are using sub lethal rates of clopyralid which only suppresses weeds to obtain mediocre control.



05 • FAN 320 329-4172

63550 CTY RD 21, P.O. BOX 500, RENVILLE, MN 56284-0500 + 320-329-8305 + FAK 320-329-8

OUTHERN MINNESOTA BEET SUGAR COOPERATIV

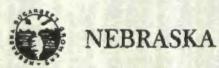
Ms. Marcia E Mulky Page 2 February 12, 2003

Our board of directors has informed me that AgValue-Clopyr, LLC applied for the Section 3 registration for clopyralid technical and Clopyr Ag. An expedited review of this additional source of clopyralid would be a great asset to my sugarbeet growers to help eliminate the supply issues that occur every year. Immediate registration of this product would allow time for AgValue to formulate the product and have it available for my growers by April.

Thank you for your consideration on behalf of the Southern Minnesota Sugar Growers.

Sincerely,

Mike Hofer



### SUGARBEET GROWERS ASSOCIATION

115 Railway Street

Sconsbluff, NE 69361

7

February 10, 2003

Phone/Fax (308) 632-4988

Mr. Bob Busch President Nebraska Beet Growers Assn. 120265 CR J Mitchell, NE 69357

Ms. Marcia E. Mulky
Director
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

RE: Clopyralid Registration by AgValue-Clopyr, LLC

Dear Ms. Mulky:

Our Sugar Beet Growers Association represents the distributors and growers of sugar beets in the Western Panhandle of Nebraska and Eastern Wyoming.

Proper weed management in sugar beet production with herbicides has resulted in greatly reducing water, light and nutrient resources, and contributed to increased crop production of sugar beets and further increased the yield and sugar content significantly in the beets. It is estimated that weeds account for up to 20% yield losses of the sugar beet crop, when not controlled properly.

Herbicides used in weed management are in short supply and clopyralid is one of the most widely used herbicides for controlling the post-emergent weeds in sugar beet crop cultivation. We recognize that there are inconsistent supplies of clopyralid. Growers rely heavily upon clopyralid for consistent and efficient weed control. A secondary source would be a great asset, if it is readily available for the growing season which begins April 1, 2003.

We understand that AgValue-Clopyr, LLC applied for the registration of clopyralid technical and also for ClOPYR AG (end-use product).

We request the Agency to grant the registration of these two products without delay so that the sugar beet grower community would benefit with the timely availability of adequate supply of this product.

Thanks for your consideration of our request.

Sincerely,

Polish Bush

president.

February 12, 2003



101 North Third Street Moorhead, Minnosoto 56560-1990

Phone: 218-236-4400

Ms. Marcia E. Mulky Director, Office of Pesticide Programs US Environmental Protection Agency Washington, DC 20460

Dear Ms. Mulky:

American Crystal Sugar Company produces about 500,000 acres of sugarbeets annually. The annual survey of production practices conducted by Dr. Alan Dexter at North Dakota State University has indicated weeds were the most serious production problem in 22 of the last 26 years. We estimate losses of over 20 million dollars annually to inadequate weed control. Post emergence applications of herbicides is a widely accepted practice by American Crystal Sugar Company growers.

The Ag Value, Inc. Company has recently become an additional supplier of herbicides to our producers. Clopyralid is a key herbicide ingredient that is used in multiple applications of herbicide on sugarbeets each year. I understand that Ag Value – Clopyr, Inc. has applied for a Section 3 registration for Clopyralid technical material and Clopyr Ag. It would be of great benefit to the sugarbeet industry of Minnesota and North Dakota if EPA could expedite this registration for the 2003 growing season. This registration would ensure consistent supplies for growers.

Please contact me at your convenience if I can be of any further assistance.

Sincerely,

Allan Cattanach General Agronomist

AC:cs

cc: Joanne Miller David Berg February 7, 2002

Ms. Marcia E Mulky Director Office of Pesticide Programs United States Environmental Protection Agency

Dear Ms. Mulky,

I am a sugarbeet grower in the state of Minnesota. My family and I have been raising sugarbeets for several years. During this time, we have implemented the most technologically advanced production methods available to insure a high quality sugarbeet crop. One of our key production problems is weed control, which varies greatly by weed species and pressure from year to year. This great variability leads to several supply chain shortages for many of the pesticides that I use each year as the manufacturers do not like to have excess inventories at the end of the spring on a minor use crop like sugarbeets. Unfortunately this inhibits my ability as a farmer to produce the crop that I want to produce each year, as I end up using sub-lethal doses of clopyralid to suppress my wild buckwheat and other weeds.

I heard from our growers' association that AgValue-Clopyr, LLC has applied for a clopyralid registration. It would benefit the sugarbeet growers greatly if an additional source of clopyralid was available to us for the 2003 growing season. Thank you for your assistance to the sugarbeet growers.

Sincerely

Kevin Martin

Martin Farms, Inc.

4532 40th Ave S

Moorhead, MN 56560

Joanne Miller

01/28/2003 10:28 AM

To: Bhushan Mandava < Mandava@compuserve.com>

cc: Bhushan Mandava <103733.1102@compuserve.com>, Deborah

McCall/DC/USEPA/US@EPA, Shyam

Mathur/DC/USEPA/US@EPA, James Stone/DC/USEPA/US@EPA

Subject: Re: Meeting Request

Dr. Mandava,

I have set up a meeting on Monday, February 3rd from 11 AM to Noon, in room 205 at CM-2. If you have a conflict with this schedule, please let me know.

Joanne I. Miller Herbicide Branch U.S. EPA

Bhushan Mandava < Mandava@compuserve.com>



Bhushan Mandava <Mandava@compuser ve.com>

01/27/03 02:59 PM

To: Joanne Miller/DC/USEPA/US@EPA

cc: Bhushan Mandava <103733.1102@compuserve.com>

Subject: Meeting Request

January 27, 2003

Ms. Joanne I. Miller (PM 23) Herbicide Branch Registration Division (7505C) U.S. Environmental Protection Agency Washington, DC 20460

SUBJECT: Registration Applications for Clopryalid Technical and Its End-Use Products

Meeting Request

Dear Ms. Miller:

On behalf of AgValue-Clopyr, LLC, I request a meeting with you and the officials from Technical Review Branch (TRB) to discuss the issues related to the registration applications for Clopyralid Technical (EPA File Symbol: 75147-G) and other end-use products containing clopyralid (File Symbols: 75147-A, E, U, R and L).

Meeting Dates: Any day next week - January 27-31, 2003

(depending on the convenience to you and other officials

in TRB)

Meeting Time: Any time - Morning (10:00 AM - 12.00 Noon) or Afternoon

(1:00 PM - 3:30 PM)

(depending on your convenience and conference room

availability)

Meeting Participants: Representing EPA from TRB

Ms. D. McCall and Dr. S. Mathur

Ms. J. Miller and Mr. J. Stone from HB

Representing AgValue-Clopyr, LLC - Bhushan Mandava

I would greatly appreciate it if you would arrange this meeting at your convenience. Thanks for your cooperation.

Sincerely,

, i, i+

Bhushan Mandava Agent for AgValue-Clopyr, LLC c/o Mandava Associates 1730 M Street, NW / Suite 906 Washington, DC 20036

Phone: 202-223-1424 Fax: 202-223-0141

E-Mail: Mandava@compuserve.com



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JAN 7 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

AgValue-Clopyr, LLC c/o Mandava Associates 1730 M Street, N.W., Suite 906 Washington, D.C. 20036

Gentlemen:

Subject:

Application for Registration

Clopyralid Technical

EPA File Symbol 75147-G

Your Submission Dated August 28, 2002

The application referred to above has been determined, pursuant to 40 CFR 152.105, not to be sufficiently complete to process; therefore, the application is considered deficient. Labeling/other information as specified below must be submitted before the processing of the application can be completed. If such deficiencies cannot be corrected within 75 days, you must notify the Agency within those 75 days of the date you expect to complete the application. If, after 75 days, you do not respond, or you subsequently fail to complete the application within the time scheduled for completion, the Agency will terminate any action on the application, and will treat the application as if it has been withdrawn by the applicant. Any subsequent submission relating to the application must be submitted as a new application.

- 1. Technical Review Branch, Registration Division has completed the product chemistry review and we have the following comments:
  - a. There is a significant difference in the density values of the proposed product [31.2 lbs/cu.ft.] and the registered product. Verify the accuracy of measurement of the density of Clopyralid produced by
  - b. Submit a updated Confidential Statement of Formula with the following corrections:
    - i. The lower certified limit of the first impurity listed on the CSF is incorrect and must be deleted from the CSF.
    - ii. Specify the Total Weight in Box 17.
    - lii. The % by weight column 13.b. must total 100%
  - c. You must conduct one year storage stability [830.6317] and corrosion characteristics [830.6320] studies under warehouse conditions in commercial containers. The results of these studies must be submitted to the Agency upon completion.

- 3. Submit five draft labels with the following corrections:
- a. If all of the Precautionary Statements do not appear on the front panel, add a referral statement similar to the following:

See side panel for additional precautionary statements

- b. At the beginning of the Hazards to Humans section add "Corrosive".
- c. In the Manufacturing Use Only section delete "trees", "industrial sites", "non-cropland", rights-of-way" and "turf". Delete the comma "," between sugar and beets.
- d. If you intend this product to be use to manufacture herbicides for non-agricultural uses, add a section similar to the following:

For manufacture of herbicides for use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial sites, non-cropland, parks, rights-of-way, and roadsides.

This product must not be formulated into manufacturing-use products or end-use herbicide products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the formulated product label must contain the following statements:

- Do not use on residential turf
- Do not send clippings to a compost facility
- Do not collect grass clippings for mulch or compost
- Applicator must give notice to landowners/property mangers to not use grass clippings for composting.

If you have any questions concerning this letter, please contact Mr. James Stone at 703-305-7391.

Sincerely yours,

Joanne I. Miller Product Manager (23)

Herbicide Branch

Registration Division (7505C)

(DRAFT LABEL)

# AGVALUE CLOPYRALID TECHNICAL

ACTIVE INGREDIENT:		
Clopyralid: 3,6-dichloro-2-pyridinecarboxylic acid		96.0%
INERT INGREDIENTS:		
TOTAL	1	00.0%

# KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID				
If in eyes:	<ul> <li>Hold eye open and rinse slowly with a steady, gentle stream of water for 15-20 minutes.</li> <li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>			
If swallowed:	<ul> <li>Call a physician or poison control center immediately for treatment advice</li> <li>Have person sip a glass of water if able to swallow.</li> <li>DO NOT induce vomiting unless told to do so by poison control center or physician.</li> <li>Do not give anything by mouth to an unconscious person.</li> </ul>			
If inhaled:	<ul> <li>Move person to fresh air.</li> <li>If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably, mouth-to-mouth, if possible.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>			
If on skin or : clothing	<ul> <li>Take off contaminated clothing.</li> <li>Wash skin with plenty of water for 15-20 minutes.</li> <li>Call a poison control center or physician for treatment advice.</li> </ul>			
Have the product	t container or label with you when calling a poison control center or			

Net Contents: 20 KG

EPA Est. No. EPA Reg. No. 75147-

Manufactured For:
AgValue-Clopyr, LLC
Visalia, CA 93291

Telemen Statemat

Doubell

#### PRECAUTIONARY STATEMENTS



## Hazard to Humans and Domestic Animals **DANGER**

Causes irreverible eye damage. Harmful is absorbed through skin or inhaled. Do not get in eyes or on skin and clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board of Regional Office of the EPA.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For Manufacturing Use Only

For formulation into an end-use herbicide only for use on asparagus, barley trees, corn, fallow land, grasses, industrial sites, mint, non-cropland, pats, pasture rights-of-way, rangeland, sugar, beets, turf, wheat. Because of their properties and intended uses, herbicidal formulations containing Clopyralid Technical herbicide will require precautionary labeling differing from that given. Formulators using this product should develop their own use and precautionary labeling, based on the properties and intended uses of their own finished formulations, and are responsible for obtaining EPA registration of these products.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

#### PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

### CONTAINER DISPOSAL

Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities.

67

DP BARCODE: D285622

14164

CASE: 067389 SUBMISSION: S621885 DATA PACKAGE RECORD

BEAN SHEET

DATE: 09/20/02 Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

ACTION: 165 NEW PROD-OC-MINOR CHG CASE TYPE: REGISTRATION

RANKING : 10 POINTS ()

CHEMICALS: 117403 Clopyralid (ANSI)

96.0000%

ID#: 075147-G AGVALUE CLOPYRALID TECHNICAL

COMPANY: 075147 AGVALUE-CLOPYR, LLC

PRODUCT MANAGER: 23 JOANNE MILLER 703-305-6224 ROOM: CM2 237 703-305-7391 ROOM: CM2 257 JAMES STONE PM TEAM REVIEWER:

RECEIVED DATE: 09/03/02 DUE OUT DATE: 03/02/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

P BARCODE: 285622 EXPEDITE: N DATE SENT: 09/20/02 DATE RET.: / /

HEMICAL: 117403 Clopyralid (ANSI)

DP TYPE: 001 Submission Related Data Package

LABEL: Y CSF: Y

ASSIGNED TO DATE IN DATE OUT DIV : RD BRAN: TRB

SECT: CHEM

REVR : S.B. Mateur 12/16/02 CONTR:

ADMIN DUE DATE: 02/07/03 NEGOT DATE: 12/29/02

PROJ DATE:

\* \* \* DATA REVIEW INSTRUCTIONS \* \*

Application for Registration of new unregistered source of clopyralid. Review product chemistry data. Process according to enclosed SOP 3068.2

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION TRB/TOX 285623

DATE OUT 09/20/02

DUE BACK 02/07/03

INS Y

CSF Y

LABEL Y

62719-80

Date: December 27, 2002

SUBJECT: Product Chemistry Review of AGVALUE Clopyralid Technical

FROM: Shyam B. Mathur, Ph.D

**Product Chemistry Team** 

Technical Review Branch/RD (7505C)

TO: Joanne Miller / James Stone, PM 23

Herbicide Branch / RD (7505C)

DP BARCODE: D285622 EPA REG. NO.: 75147-G

REGISTRANT: AGVALUE-CLOPYR, LLC

USE: Herbicide

### INTRODUCTION:

The registrant has submitted the product chemistry data to support the registration of Agvalue Clopyralid technical produced. This product may be used only for the formulation of end use herbicide products for the use on : asparagus, barley, trees, corn, fallow land, grasses, industrial sites, mint, non-cropland, oats, pasture, rights-of-way, rangeland, sugar, beets, turf, and wheat. The registrant has claimed that the proposed technical is substantially similar to the registered technical product with Reg. No. 62719-80.

8/8/12-27-07

The product chemistry data for the Agvalue Clopyralid technical are submitted under MRID Nos.: 457515-01 through 457515-04 and 457556-01.

For analysis, has provided five production batches of Clopyralid technical to Stillmeadow Incorporation in Texas, USA. also did independent five batch analysis of the technical.

### **SUMMARY OF FINDINGS:**

- 1. The registrant has submitted the Confidential Statement of Formula for basic formulation (dated 08-28-02), for Clopyralid technical. The nominal concentration (96.0%) of the Al agrees with the product label claim nominal concentration. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.
- 2. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160. The registrant has provided the product specifications data on all the starting materials used for the production of this herbicide. [MRID No. 457556-01]
- 3. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162. The registrant has provided the details of the manufacturing process. [MRID No. 457556-01]
- 4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities)satisfy the data requirements for 40CFR§158.167. [MRID No. 457556-01]
- 5. The data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. Five representative lots of the technical were analyzed for percent active ingredient by GC/FID method, and other impurities present at levels of 0.1% or greater were determined by HPLC method by and Stillmeadow. The method was validated for Accuracy, Linearity, and Precision. [MRID No. 457515-01,457515-02, and 457556-01]

- **6.** The data submitted corresponding the guideline reference 830.1800 (Enforcement Analytical method) satisfy the data requirements of 40CFR§158.180. The HPLC / UV for method impurities and GC/FID method was used to assay the active ingredient in the technical. The methods were validated for accuracy, linearity, and precision. [MRID No. 457515-01].
- **8.** The registrant has submitted product chemistry data corresponding to guideline reference 830 Series Subgroup B (Physical/Chemical properties) for the technical. The data submitted satisfy the data requirements of 40CFR 158.190. [MRID Nos. 457515-03 and 457515-04].

### CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the AgValue Clopyralid technical and has concluded that:

- 1. All the product chemistry data submitted corresponding to 830 Series Subgroup A and Subgroup B satisfy the data requirements of 40CFR§158.155 to 158.190 and are acceptable, except the CSF for basic formulation.
- 2. The CSF for basic formulation (dated 08-28-02) is not filled out correctly and completely. It is in compliance with PR Notice 91-2. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF for basic formulation is not acceptable for the following reasons:
- i. The lower certified limit for one impurity provided is incorrect, it must be deleted from the CSF.
- ii. The total weight in Block #17 of CSF has not been provided.
- 3. The applicant must conduct one year storage stability (830.6317) and corrosion characteristics (830.6320) studies under warehouse conditions in commercial containers. The results of these studies must be submitted to the Agency on completion.
- 4. The proposed technical (75147-G) was determined to be substantially similar to the registered product with Reg. No.62719 -80 from the product chemistry point of view. The manufacturing process adopted produces more environmental friendly product with less number of impurities than the registered product. However, it is important to mention that there is significant difference in the density values of the proposed and registered products. (Registered product d = 18.6 lbs/cu. ft; for the proposed product d = 31.2 lbs/cu.ft).

Note to PM: The registrant must be asked about the accuracy of measurement of density of the Clopyralid produced by

5. The data corresponding to 830 Series Subgroup B (Physical / Chemical properties) for Clopyralid technical were generated at Stillmeadow Incorporation, TX, USA (MRID No. 457515-04) and were also submitted by under MRID No. 457515-03. In this report only the MRID No.

457515-03 has been shown.

BARCODE: <u>D285622</u>; Reg. No. : <u>75147-G</u> PRODUCT: <u>AgValue Clopyralid Technical</u>

830.1550. Product Identity: [MRID No. 457556-01]

Common Name: AgValue Clopyralid Technical

Chemical Name: (CA): 3,6-Dichloro-2-pyridinecarboxylic acid

Synonymus: 3,6-Dichloropicolinic acid (IUPAC); 3, 6-Dichloropyridine-2-carboxylic acid

CAS No.: 1702-17-6

PC Code No.: 117403

Empirical formula: C<sub>6</sub> H<sub>3</sub> NO<sub>2</sub> Cl<sub>2</sub>

Molecular Weight: 192

Structural formula:

# ATTACHMENT II REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	3,6-Dichloro-2-pyridinecarboxylic acid
Chemical Number (CAS; PC Code)	CAS No. 1702-17-6 PC Code No.: 117403
Registration/Symbol No.	75147-G
Type of Product (T, MP, EP)	96.0% TGAI / MP
DP Barcode	D285622
Reviewer	Shyam B. Mathur
Branch Chief	Deborah McCail

GLN	Requirement	MRID	Status <sup>1</sup>	Details and/or Deficiency <sup>2</sup>
830.1550	Product identity and composition	Basic CSF (08-28-02))	N	The NC of Al concurs with the product label claim and is supported by 5 batch analysis. The LCL for 1 impurity is incorrect and no total wt. Block #17 was provided
830.1600	Description of materials used to produce product	457556-01	Y	The product specification sheets(MSDS) for all the starting materials have been provided by
830.1620 Description of production process		457556-01	Y	The registrant has provided detailed information about the synthesis of the technical. The amounts of each starting material and conditions under which the reaction were performed are provided.
830.1670	Discussion of formation of impurities	457556-01	Y	The registrant has provided required information on the formation of impurities. The mechanisms for the formation of impurities during different stages of the production process have been submitted.
830.1700	Preliminary analysis	457556-01 457515-01(S) 457515-02(S)	>	Registrant has provided 5 batch analysis for the TGAI. For TGAI the GC / FID method was used and the HPLC / UV (254 nm)method used for impurities. The reverse phase HPLV / UV (254 nm), HPLC / MS were also used to identify and quantify the AI and impurities. The analytical method was validated for linearity, accuracy and precision. The analysis by Stillmeadow(S) assayed the AI which exceeds 97%, whereas indicated clopyralid at > 96% purity.
830.1750	Certified limits	Basic CSF (08-28-02)	υ	The certified limits for the TGAI were within the standard certified limits. The limits were verified by 5 batch analysis. The NC's and UCLs for impurities have been provided. For one impurity, the LCL is incorrect.
830.1800	Enforcement analytical method	457556-01	Y	The GC / FID method used for the assay of the Al. The method validated for accuracy, linearity, & precision.

GLN	Requirement	MRID	Status <sup>1</sup>	Result <sup>2</sup> or Deficiency
830.6302	Color	457515-03	А	Off-white
830.6303	Physical state	tt 19	44	Solid powdery lump
830.6304	Odor	st 19		No apparent odor at distance of 10 "; at 5 " a sligh wet moldy rag odor
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	и п	u	stable to elevated temperatures; stable in presence of Fe powder, Pb shot, Ferric chloride, & lead nitrate
830.6314	Oxidation/reduction: chemical incompatibility	ll 77	u	The TS was stable to oxidizing & reducing agents(when tested with water, carbon dioxide, elemental Fe, bleach and gasoline)
830.6315	Flammability	a n	w	waiver accepted
830.6316	Explodability	u n	w	waiver accepted
830.6317	Storage stability	457515-03	ı	Accelerated study for 14 days at 54C indicate that TS is stable. One year study must be conducted.
830.6319	Miscibility	NA	u	
830.6320	Corrosion characteristi	457515-03	tt	non-corrosive to Fe. One year must be conducted
830.7000	рН	457515-03	w	TS non-dispersible and not soluble in water so pH could not be measured. Waiver accepted
830.7050	UV/Visible absorption	457515-03	А	See Note 1
830.7100	Viscosity	NA NA	tt	
830.7200	Melting point/ Melting range	457515-03	А	155C ( range of 154-156C; Stillmeadow) 151-152C
830.7220	Boiling point/ Boiling range	NA		
830.7300	Density/ relative density/ bulk density	457515-03	U	0.501 g/ml at 20C
830.7370	Dissociation constants in water	и	А	pKa = 2.0
830.7550	Partition coefficient (n-octanol/water), shake flask method	и	А	log Po/w = 2 0 (by HPLC method ; Stillmeadow) See Note 2
830.7840	Water solubility: column elution method; shake flask method	u	A	water = 0.048 ppm at 20C (Stillmeadow) See Note 2
830.7950	Vapor pressure	n	Α	1.33 mPa (PAI at 24C); 1.36 mPa(TGAI at 25C)

A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable; G = Data gap 'W = waiver request I = Incomplete or in progress

## Note 1. 830.7050. UV/VIS:

The UV/VIS absorption spectra for the TS were recorded in MeOH, basic MeOH, and acidic MeOH.

Solvent	<u>λ max</u>	Molar Absorption coefficient (cm² / mole)
Methanol-Water (neutral)	223 nm 280 nm	9255 4747
Acidic MeOH-Water	227 nm 282 nm	8650 3582
Alkaline MeOH-Water	220 nm 281 nm	9161 4700

The pH has no effect (or negligible effect) on the UV/Visible absorption spectra for the TS (Clopyralid)

## Note 2. Partition coefficient. 830.7570:

Log Po/w: 2.00 by HPLC method (according to Stillmeadow)

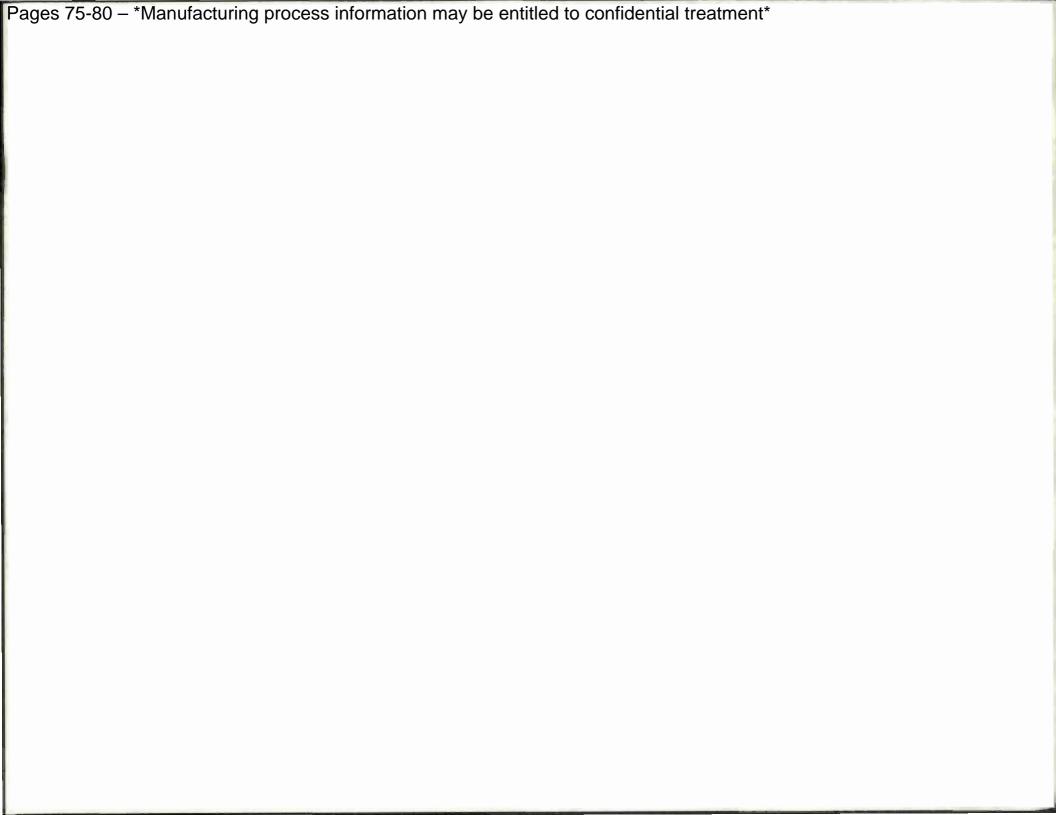
Log Po/w: 1.81 (pH = 5), 2.63 (pH = 7), 2.55 (pH = 9), and 1.07 (unionized at 25C) [data provided by

## Note 3. Solubility in water. 830.7840/60:

0.048 ppm at 20C (Stillmeadow)

Solubility in organic solvents (by

n-hexane = 6 g/l; Acetonitrile = 121 g/l; MeOH = 104 g/l





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

# OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

# TECHNICAL REVIEW BRANCH SIMILARITY CLINIC DETERMINATION

09/DEC//2002

Subject:

EPA Reg. No./File Symbol:

75147-G Clopyralid Technical

DP Barcode:

D285623

Case No:

067389

PC Code:

117403

From:

Masih Hashim, Toxicologist

Technical Review Branch

Registration Division (7505 C)

To:

James Stone, PM Team 23

Herbicide Branch

Registration Division (7505C)

Applicant:

AgValue-Clopyr, LLC

Visalia, CA 93291

ACTION REQUESTED: PM requests similarity action between the proposed product 75147-G and the cited EPA Reg. No. 62719-80. The common active ingredient is Clopyralid.

Recommendations: TRB has evaluated the proposed and the cited products and we consider them to be essentially similar. The data can be bridged between them. The Signal Word is Caution.

This memorandum only pertains to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no determinations of the adequacy of the toxicological data base or the precautionary label of the cited product.

14140

DP BARCODE: D285623

CASE: 067389 SUBMISSION: S621885

CONTR:

DATA PACKAGE RECORD

BEAN SHEET

DATE: 09/20/02

Page 1 of 1

\* \* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 165 NEW PROD-OC-MINOR CHG

RANKING: 10 POINTS ()

CHEMICALS: 117403 Clopyralid (ANSI)

96.0000%

ID#: 075147-G AGVALUE CLOPYRALID TECHNICAL

COMPANY: 075147 AGVALUE-CLOPYR, LLC

PRODUCT MANAGER: 23 JOANNE MILLER
703-305-6224 ROOM: CM2 237
PM TEAM REVIEWER: JAMES STONE 703-305-7391 ROOM: CM2 257

RECEIVED DATE: 09/03/02 DUE OUT DATE: 03/02/03

\* \* \* DATA PACKAGE INFORMATION \* \* \*

BARCODE: 285623 EXPEDITE: N DATE SENT: 09/20/02 DATE RET.: / /

HEMICAL: 117403 Clopyralid (ANSI)

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT
DIV: RD // //
BRAN: TRB // //
SECT: TOX // //
REVR:

ADMIN DUE DATE: 02/07/03 NEGOT DATE: 12/24/0~

PROJ DATE: / /

\* \* \* DATA REVIEW INSTRUCTIONS \* \* \*

For Similarity Clinic New unregistered source of clopyralid. Using cite-all method of support. Is product substantially similar to registered technical EPA Reg. No. 62719-80?

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL 285622 TRB/CHEM 09/20/02 02/07/03 Y Y Y

## U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

AGVALUE-CLOPYR, LLC C/O MANDAVA ASSOCIATES 1730 M STREET, N.W. SUITE 906 WASHINGTON, DC 200364512

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/03/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# MANDAVA ASSOCIATES

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-Mail: mandava@compuserve.com

## Hand Delivered

August 28, 2002

Ms. Joanne I. Miller
Product Manager 23
Herbicide Branch
Registration Division (7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

75147-6

SUBJECT:

ME-TOO Application for Registration for AgValue CLOPYRALID

**TECHNICAL** 

Active Ingredient: Clopyralid EPA Chemical Code: 117403

Company Name: AgValue-Clopyr, LLC

Company Number: 75147

Dear Ms. Miller:

On behalf of AgValue-Clopyr, LLC, we are submitting a ME-TOO application for the registration of AgValue CLOPYRALID TECHNICAL which is the trade name for clopyralid technical.

In support of the application for the subject product registration, we are providing the following administrative materials and product chemistry data on AgValue CLOPYRALID TECHNICAL"

- 1) Authorization Letter designating us as an Agent
- 2) Application for Pesticide Registration
- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Data Matrix
- 6) Five Copies of Draft Labeling for the Subject Product

7)	Volume 1:	AgValue CLOPYRALID TECHNICAL: Group A - Product
		Identity, Composition, and Analysis. Product Properties Data in
	45755601	Support of FIFRA Registration. Data Requirement: 40 CFR
		158.155-180; OPPTS Test Guidelines 830.1000-1900; OPP
		Guideline Series 61 and 62 (Project No.: AVI-CLOPYR TECH-
		PC-1); AgValue-Clopyr, LLC

8) Volume 2A: AgValue CLOPYRALID TECHNICAL: Group A - Product Identity, Composition, and Analysis. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR 158.155-180; OPPTS Test Guidelines 830.1000-1900; OPP Guideline Series 61 and 62 (Project No.: AVI-CLOPYR TECH-PC-2); AgValue-Clopyr, LLC

9) Volume 2B: Clopyralid Technical: Chemical Characterization of a Test Substance to Determine Amounts of Active Ingredient (OPPTS Series 830 Sections 1700); Stillmeadow Laboratory Study Number 6824-01; AgValue-Clopyr, LLC

10) Volume 3A: AgValue CLOPYRALID TECHNICAL: Group B - Physical and Chemical Properties. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR 158.190; OPPTS Test Guidelines 830.6302-7950; OPP Guideline Series 63 (Project No.: AVI-CLOPYR TECH-PC-3); AgValue-Clopyr, LLC

11) Volume 3B: Clopyralid Technical: Product Chemistry: Technical Grade Product (OPPTS Series 830 Sections 6302, 6303, 6304, 6313, 6314, 6315, 6325, 7000, 7200, 7300, 7570 and 7840); Stillmeadow Laboratory Study Number 6825-01; AgValue-Clopyr, LLC

This product chemistry data was developed by AgValue-Clopyr, LLC in support of the application for registration for the subject product.

Please also note that AgValue-Clopyr, LLC is relying on the safety data submitted by other registrants on clopyralid. In accordance with the regulations under 40 CFR Part 152, the applicant has:

1) Notified all persons listed in "Data Submitters List" regarding his intention to apply for the subject registration and with an offer to pay compensation for the applicable data to the extent required by FIFRA section 3(c)(1)(D); and,

2) Selected "cite-all" method of support and general offer to pay (EPA Form 8570-34 and EPA Form 8570-350).

In addition to the above studies, we are also relying on other items of data on the subject product in the Agency's files.

We are requesting an "Expedited Review" in accordance with FIFRA Section 3(c)(3)(b)(i), because our product (AgValue CLOPYRALID TECHNICAL) is substantially similar or identical in composition and labeling to Lontrel T (EPA Reg. No.: 464-613) which contains 95% clopyralid as an active ingredient.

Since we have fulfilled all the registration requirements, we request you grant the registration for the subject product, so that the applicant can market it for the next growing season.

Sincerely,

N. Bhushan Mandeve

N. Bhushan Mandava, Ph.D., RAC Agent for AgValue-Clopyr, LLC

Enclosure

cc: Brian Heinze



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

09/06/2002

N. BUSHAN MANDAVA MANDAVA ASSOCIATES 1730 M STREET, N.W., SUITE 906 WASHINGTON DC 200364510

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: AGVALUE CLOPYRALID TECHNICAL

COMPANY NAME: MANDAVA ASSOCIATES OPP IDENTIFICATION NUMBER: 279672

EPA FILE SYMBOL: 75147-G EPA RECEIPT DATE: 09/03/2002

SUBJECT: RECEIPT OF APPLICATION FOR A NEW ME-TOO REGISTRATION

### DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new 'me-too' registration and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Joanne Miller, Product Manager 23, at (703)-305-6224.

Sincerely,

Furue

Front End Processing Staff
Information Services Branch
Program Management and Support Division

# SUBMISSION TRACKING RECORD

BAR CODE 5 621885	ID NUMBER	15147-6
ACTION CODE 165	PM 23	
TEAM REVIEWER		
DATE ON APPLICATION 8 1281 02		
EPA RECEIVED DATE 9,6,02		
PM RECEIVED DATE 9/18/02		
SPECIAL INSTRUCTIONS:		
<b>«</b>		
FINAL ACTION		
RESPONSE CODE RESPO	ONSE DATE	

Form Approved, OMB No. 2070-0060, Approvel expires 2-28-95

United States

# SEPA Environmental Protection Agency

~	Registration
	Amendment
	Other

**OPP Identifier Number** 

770177

	Washington, DC 20	460			Other	T.	217612
	Application	on for Pe	sticid	e - Section	n I		
1. Company/Product Number 75147-			. EPA Pr	roduct Manager Miller		3. Pr	oposed Classification
4. Company/Product (Name) AgValue Clopyralid Technical			M# 23				Note I nestricted
5. Name and Address of Applicant (Included AgValue-Clopyr, LLC c/o Mandava Associates 1730 M Street, N.W., Sui Washington, D.C. 20036 Check If this is a new address.	te 906	(b	o)(i), my o: EPA Re	product is si eg. No. 627	milar or iden	tical in co	FIFRA Section 3(c)(3) imposition and labeling
		Sectio	n - II				
Amendment - Explain below.  Resubmission in response to Ages  Notification - Explain below.  Explanation: Use additional page(s) if		n I and Sectio		Final printed lab Agency latter d "Ma Too" Appli Other - Explain	ated ication.	se to	
		Section	n - III				• • •
1. Material This Product Will Be Package	f ln:	300410					
Child-Resistent Packaging  Yes  No  Pertification must be submitted  Unit Packaging  Unit Packaging  Unit Packaging  Unit Packaging	No. per	Water Sol  Ye  No  If "Yes"  Package v	0	No. per container	2. Type of	Metal Plastic Glass Paper Other (S	
3. Location of Net Contents Information  Label Container	4. Size(s) Re	tail Container 20 kg		5. (	Location of La	bel Direction	ons
6. Manner in Which Label is Affixed to Pr	Lithog Paper Stend	graph glued iiled		Other _			
		Section	n - IV				
1. Contact Point (Complete items direct)	below for identification	on of individue	al to be	contacted, if no	ecessary, to p	rocess this	application.)
Name N. Bhushan Mandava, Ph.D.		Title Agent for A	\gValue	-Clopyr, LLC.			e No. (Include Area Code) 3-1424
I certify that the statements I have I acknowledge that any knowlingly both under applicable law.		all attechme					6. Date Application Received  •• (Stamped)
2. Signature N. Bhustan Han	dave	3. Title Agent for AgValue-Clopyr, LLC.			••••		
4. Typed Name N. Bhushan Mandava, Ph.D.		5. Date	Augı	ust 2 <mark>8</mark> , 200	2		

## AgValue-Clopyr, LLC 1124 N. Chinowth Street Visalia, CA 93291 559-627-6956

August 28, 2002

Director
Office of Pesticide Programs
C/o document Processing Desk (COADR)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Ariel Rios Building
Washington, DC 20004

### Dear Sir/Madam:

This letter is to authorize the following party to act on behalf of AgValue-Clopyr, LLC, as our agent to represent us before the United States Environmental Protection Agency in regards to all matters pertaining to our product registrations and establishments effective the date of this letter.

MANDAVA ASSOCIATES
1730 M Street, N.W.
Suite 906
Washington, DC 20036-4510
Phone (202) 223-1747/1424
Fax: (202) 223-0141
Contest across N. Puchen Manday

Contact person: N. Bushan Mandava, Ph.D.

We acknowledge that all official correspondence from the EPA, Office of Pesticide Programs will be directed to the agent at the address as listed above.

This appointment is to remain in effect until revoked by us in writing.

Very truly yours,

G. Steven Bratcher
LLC Member



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.

Information Management Division (2137), U.S. Environmental Protection Agency, 40 Do not send the completed form to this address.	1 M Street, S.W., W	asnington, DC 20460.		
Certification with Respec	t to Citation of	Data		
Applicant's/Registrant's Name, Address, and Telephone Number AgValue-Clopyr,LLC, 1124 N. Chinowth Ave., Visalia, CA 93291 (1-866-511-3171	1)	EPA Registration Number/File Symbo 75147-	ol	
Active Ingredient(s) and/or representative test compound(s) Clopyralid (CAS# 1702-17-6)		Date August 28, 2002		
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 TGAI, MUP	3)	Product Name AgValue Clopyralid Technical		
NOTE: If your product is a 100% repackaging of another purchased EPA-register submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator)		or all the same uses on your label, yes	not need to	
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies se	nt offers of compensation (the Data Ma	trix form should	
SECTION I: METHOD OF DATA SUPI	PORT (Check one m	ethod only)	:	
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	I am using under the completed used).	g the selective method of support (or ci selective method), and have included d list of data requirements (the Data Ma	te-all option with this form a structorm must be	
SECTION II: GENERAL	OFFER TO PAY			
SECTION III: CERT	TIFICATION	15.0		
I certify that this application for registration, this form for reregistration, or the pata-Call-in response. It indicated in Section I, this application is supported by all data in the Agency's files the substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sources.  I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.  I certify that for each study cited in support of this registration or reregistrate submitter; (b) I have obtained the permission of the original data submitter to use the compensation have expired for the study; (d) the study is in the public literature; or (e) offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(amount and terms of compensation, if any, to be paid for the use of the study.  I certify that in all instances where an offer of compensation is required, co accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	his Data-Call-In responded and addition, if the cite- at (1) concern the pro- is a type of data that ght the initial registration, the concern that is not an except and in the control of	all option or cite-all option under the seleperties or effects of this product or an it would be required to be submitted undition of a product of identical or similar of at I am the original data submitter or the clusive use study, either: (a) I am the original data submitter or the clusive use study, either: (a) I am the original periods of eligibiliting the company that submitted the stand (ii) to commence negotiations to fill any compensation and evidence of the Agency upon request. Should I fail to product or an any compensation and evidence of the Agency upon request. Should I fail to product or an any compensation and evidence of the Agency upon request. Should I fail to product or an any compensation and evidence of the Agency upon request.	dective method is identical or ler the data composition and let I have obtained liginal data by for udy and have leftine the leftine the leftine the leftine in groduce such	
I certify that the statements I have made on this form and all attachn knowingly false or misleading statement may be punishable by fine or imprise	nents to it are true, onment or both und	accurate, and complete. I acknowled applicable law.	edge that any	
Signature N. Blustian Plandow	Date August 28, 2002	Typed or Printed Name and Title N. Bhushan Mandava, Agent for Ag	JValue-Clopyr, LL	





### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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		DATA MATRIX			
Date August 28, 2002 EPA Reg No./File Symbol 75147  Applicant's/Registrant's Name & Address AgValue-Clopyr, LLC., 1124 N. Chinowth Ave., Visalia, CA 93291 AgValue Clopyralid Technical		EPA Reg No./File Symbol 75147		Page 1 of 1	
Ingredient Clopyralid (CAS# 1702-1	7-6)		117403		
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Cite All			Riverdale Chemical Co., 1333 Burr Ridge Pkwy.	Pay	
			Burr Ridge, IL 60572 (Company# 228)		
			Lebanon Seaboard Corp., 1600 E. Cumberland	Pay	
			St., Lebanon, PA 17042 (Company# 961)		
			Dow Agrosciences LLC, 9330 Zionsville Rd	Pay	
			Indianapolis, IN 46262 (Company# 62719)		
· · · · · · · · · · · · · · · · · · ·			Spray Drift Task Force, Mckenna & Cuneo LLP	Pay	
			1900 K Street, NW, Washington DC, 20006		
			(Company No. 066607)		
			Beveridge & Diamond, P.C. Agent for Outdoor	Pay	
			Residentail Exposure, 1350 I Street, NW.		
			Washington, DC 20005 (Company# 71754)		
			Beveridge & Diamond, P.C. Agent for Agricult-	Pay	
••• • •			urall Re-entry Task Force, 1350 I Street, NW.		
			Washington, DC 20005 (Company# 71755)		
Signature IV. Blunch	an Mandava		Name and Title  N. Bhushan Mandava, Agent for AgValue-Clopy	r, LLC	Date 08/28/2002

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

## MANDAVA ASSOCIATES

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-MAIL: Mandava@Compuserve.com

# **FAX**

DATE:

September 11, 2002

TO:

Joanne I. Miller Product Manger 23

Registration Division (7505C)

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW:

Washington, D.C. 20460

FAX NO .:

703-308-1825

SUBJECT:

AgValue CLOPYRALID TECHNICAL

EPA File Symbol #75147-G

Volume 1 (Confidential Appendix)

TOTAL PAGES:

TWO (including this Pages)

Dear Ms. Miller:

Thanks for your today's fax regarding the missing page (Page 186) in the subject Volume 1, Confidential Appendix.

I am enclosing the missing page and request you to include it in Volume 1.

Thanks for your ready cooperation.

Best Regards,

N. Bhushan Mandava

N. Bhushan Mandava Agent for AgValue-Clopyr, LLC

# U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

AGVALUE-CLOPYR, LLC C/O MANDAVA ASSOCIATES 1730 M STREET, N.W. SUITE 906 WASHINGTON, DC 200364512

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/03/02. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents. If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below. These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels. The rejected studies and their deficiencies are described below.

Rejected study [01] :

\* Judging from the pagination of the study, pages. . . . . were omitted from the submitted copy.

186 in the confidential attachment

# MANDAVA ASSOCIATES

CONSULTANTS IN SCIENCE, TECHNOLOGY AND REGULATORY AFFAIRS
1730 M STREET, N.W., SUITE 906, WASHINGTON, DC 20036-4512
TELEPHONE: (202)-223-1424/1747 · TELEFAX: (202)-223-0141 · E-Mail: mandava@compuserve.com

## Hand Delivered

August 28, 2002

Ms. Joanne I. Miller
Product Manager 23
Herbicide Branch
Registration Division (7504C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

75147-6

SUBJECT: ME-TOO Application for Registration for AgValue CLOPYRALID

TECHNICAL

Active Ingredient: Clopyralid EPA Chemical Code: 117403

Company Name: AgValue-Clopyr, LLC

Company Number: 75147

Dear Ms. Miller:

On behalf of AgValue-Clopyr, LLC, we are submitting a ME-TOO application for the registration of AgValue CLOPYRALID TECHNICAL which is the trade name for clopyralid technical.

In support of the application for the subject product registration, we are providing the following administrative materials and product chemistry data on AgValue CLOPYRALID TECHNICAL"

- 1) Authorization Letter designating us as an Agent
- 2) Application for Pesticide Registration
- 3) Confidential Statement of Formula
- 4) Certification with Respect to Citation of Data
- 5) Data Matrix
- 6) Five Copies of Draft Labeling for the Subject Product

- 7) Volume 1: AgValue CLOPYRALID TECHNICAL: Group A Product Identity, Composition, and Analysis. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR 158.155-180; OPPTS Test Guidelines 830.1000-1900; OPP Guideline Series 61 and 62 (Project No.: AVI-CLOPYR TECH-PC-1); AgValue-Clopyr, LLC
- 8) Volume 2A: AgValue CLOPYRALID TECHNICAL: Group A Product Identity, Composition, and Analysis. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR 158.155-180; OPPTS Test Guidelines 830.1000-1900; OPP Guideline Series 61 and 62 (Project No.: AVI-CLOPYR TECH-PC-2); AgValue-Clopyr, LLC
- 9) Volume 2B: Clopyralid Technical: Chemical Characterization of a Test Substance to Determine Amounts of Active Ingredient (OPPTS Series 830 Sections 1700); Stillmeadow Laboratory Study Number 6824-01; AgValue-Clopyr, LLC
- 10) Volume 3A: AgValue CLOPYRALID TECHNICAL: Group B Physical and Chemical Properties. Product Properties Data in Support of FIFRA Registration. Data Requirement: 40 CFR 158.190; OPPTS Test Guidelines 830.6302-7950; OPP Guideline Series 63 (Project No.: AVI-CLOPYR TECH-PC-3); AgValue-Clopyr, LLC
- 11) Volume 3B: Clopyralid Technical: Product Chemistry: Technical Grade Product (OPPTS Series 830 Sections 6302, 6303, 6304, 6313, 6314, 6315, 6325, 7000, 7200, 7300, 7570 and 7840); Stillmeadow Laboratory Study Number 6825-01; AgValue-Clopyr, LLC

This product chemistry data was developed by AgValue-Clopyr, LLC in support of the application for registration for the subject product.

Please also note that AgValue-Clopyr, LLC is relying on the safety data submitted by other registrants on clopyralid. In accordance with the regulations under 40 CFR Part 152, the applicant has:

1) Notified all persons listed in "Data Submitters List" regarding his intention to apply for the subject registration and with an offer to pay compensation for the applicable data to the extent required by FIFRA section 3(c)(1)(D); and,

2) Selected "cite-all" method of support and general offer to pay (EPA Form 8570-34 and EPA Form 8570-350).

In addition to the above studies, we are also relying on other items of data on the subject product in the Agency's files.

We are requesting an "Expedited Review" in accordance with FIFRA Section 3(c)(3)(b)(i), because our product (AgValue CLOPYRALID TECHNICAL) is substantially similar or identical in composition and labeling to Lontrel T (EPA Reg. No.: 464-613) which contains 95% clopyralid as an active ingredient.

Since we have fulfilled all the registration requirements, we request you grant the registration for the subject product, so that the applicant can market it for the next growing season.

Sincerely,

N. Bhushan Mandeve

N. Bhushan Mandava, Ph.D., RAC Agent for AgValue-Clopyr, LLC

Enclosure

cc: Brian Heinze

